UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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 December 31, 2024
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission File Number 001-41331

AN2 Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-0606654**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1800 El Camino Real, Suite D Menlo Park, California	**94027**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 331-9090

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, par value $0.00001 per share	ANTX	The Nasdaq Global Select Market

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 §240.10D-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 equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the Nasdaq Global Select Market on June 28, 2024, was $41,131,046.

The number of shares of Registrant's Common Stock outstanding as of March 20, 2025 was 30,098,720 shares of common stock, par value $0.00001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2025 annual meeting of stockholders is incorporated by reference in Item 5 of Part II and Items 10, 11, 12, 13 and 14 of Part III.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical and nonclinical studies and clinical trials, results of preclinical and nonclinical studies, clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue," or the negative of these terms or other similar expressions. Forward-looking statements contained in this Form 10-K include, but are not limited to, statements about:

- the initiation, timing, progress, and results of our preclinical and nonclinical studies and clinical trials, and our research and development programs, including the manufacture of clinical trial material and drug product for launch;
- the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- our use of the net proceeds from financing activities;
- the ability of our Phase 2/3 clinical trial in treatment-refractory *Mycobacterium avium* complex ("MAC") lung disease or future trials to be sufficient for regulatory approval in the United States and Japan and potentially other territories;
- the results of the blinded Phase 3 data from the truncated EBO-301 trial and the outcome of potential interactions with the FDA regarding future development in NTM, if any;
- our ability to commence studies of epetraborole in new patient populations, which regulatory authorities may not allow or authorize or may delay allowing or authorizing;
- the translation of our preclinical results and data and early clinical trial results, in particular relating to safety, efficacy and durability, into future clinical trial results;
- our ability to retain the continued service of our key professionals and to identify, hire, and retain additional qualified professionals;
- our ability to advance our initial product candidate and any other product candidates we may develop into, and successfully complete, clinical trials;
- the timing of and our ability to obtain and maintain regulatory approvals for our initial product candidate and any other product candidates we may develop;
- the commercialization of our initial product candidate and any other product candidates we may develop, if approved;
- the ability of epetraborole, if approved, to successfully compete with other therapies, including therapies currently in development;
- the size of the market opportunity for epetraborole or any other product candidates we may develop in each of the diseases we target;
- the pricing, coverage, and reimbursement of epetraborole, if approved;
- the implementation of our business model, strategic plans for our business, and our initial product candidate and any other product candidates we may develop;
- the scope of protection we are able to establish and maintain for intellectual property rights covering epetraborole and any other product candidates;

- the potential post-approval marketing exclusivities that may be granted to epetraborole and any other product candidates based upon certain regulatory designations, and other non-patent exclusivities in the United States and Japan;
- our ability to identify additional product candidates and advance them into clinical development;
- our financial performance;
- developments relating to our competitors and our industry;
- our expectations regarding the impact of inflation, macroeconomic conditions and geopolitical conflicts on our business and operations, including on our manufacturing suppliers, collaborators, contract research organizations ("CROs") and employees; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act").

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations, and prospects and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties, and assumptions described in the section titled "Risk Factors" in Part I, Item 1A and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Annual Report, whether as a result of any new information, future events, or otherwise.

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 statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

PART I

Item 1. Business.

Overview

AN2 Therapeutics, Inc. (also referred to in this document as “AN2,” “we,” the “Company” or the “Registrant”) is a biopharmaceutical company focused on discovering and developing novel small molecule therapeutics derived from our boron chemistry platform. AN2 has a pipeline of boron-based compounds in development for Chagas disease, non-tuberculous mycobacterial (“NTM”) and melioidosis, along with early-stage programs focused on targets in infectious diseases and oncology.

Our initial candidate is epetraborole, which we are studying as a potential once-daily, oral treatment with a novel mechanism of action for patients with non-tuberculous mycobacterial (“NTM”) lung disease, a rare, chronic and progressive infectious disease caused by bacteria known as mycobacteria, which leads to irreversible lung damage and can be fatal. Epetraborole is designed to produce broad-spectrum antimycobacterial activity through inhibition of an essential and universal step in bacterial protein synthesis. Its novel mechanism of action is enabled by boron chemistry, our core technology approach. We in-licensed the exclusive worldwide development and commercialization rights for epetraborole from Pfizer Inc. in 2019.

The FDA granted us Fast Track designation to investigate epetraborole for treatment-refractory MAC lung disease, Qualified Infectious Disease Product (“QIDP”) designation for treatment-refractory MAC lung disease, and orphan drug designation for the treatment of infections caused by NTM. We have also received orphan medicinal product designation from the European Commission for the treatment of NTM lung disease using epetraborole. Based on clinical and preclinical data generated with epetraborole, its novel mechanism of action, and the convenience associated with once-daily, oral dosing, we believe that epetraborole, if approved, has the potential to become an important component of a multi-drug treatment regimen for patients suffering from NTM lung disease.

Epetraborole in NTM

Our lead development target in NTM is treatment-refractory MAC lung disease, a condition with high unmet need where the mycobacterial infection persists despite standard front-line therapies. These patients represent complex cases for treatment, often presenting with structural lung damage, high levels of resistance to background therapies, and persistent symptoms that can significantly degrade quality of life. In 2023, the FDA issued a Guidance for Industry entitled, “*Nontuberculous Mycobacterial Pulmonary Disease Caused by Mycobacterium Avium Complex: Developing Drugs for Treatment Guidance for Industry*,” which among other things, recommended that new potential therapies intended for the treatment of NTM caused by MAC utilize clinical outcome assessments, such as patient-reported outcome ("PRO") measures that assess symptomatic improvement, as primary efficacy endpoints in registrational trials intended to support applications for traditional approval. To date, no drugs have been approved by FDA based on achievement of an endpoint demonstrating symptom improvement in a treatment refractory population. The only FDA-approved therapy for treatment-refractory MAC lung disease received accelerated approval based on the surrogate endpoint of sputum culture conversion without having demonstrated symptom improvement.

On August 8, 2024, we announced topline results from the Phase 2 part of EBO-301, a Phase 2/3 study evaluating epetraborole on top of optimized background regimen (“OBR”) in treatment-refractory MAC lung disease ("TR-MAC"), and terminated the Phase 3 portion of the trial early with 97 patients enrolled. The Phase 2 part of the study met its primary objective of demonstrating the potential validation of a novel PRO tool and a numerically higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19). However, sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Epetraborole was generally well tolerated in the Phase 2 portion of the trial.

The primary purpose of the Phase 2 part of the EBO-301 study was to test the validity of multiple patient-reported outcome tools in a treatment refractory population, with the goal of identifying a PRO-based primary endpoint for the Phase 3 portion of the trial. To that end, we recently submitted an amended statistical analysis plan to the FDA selecting the Quality of Life – Bronchiectasis ("QOL-B") respiratory domain patient reported outcome instrument as the primary efficacy endpoint for the Phase 3 part of the EBO-301 trial.

Using QOL-B as a continuous measure of clinical improvement, epetraborole showed nominal statistical superiority versus placebo in change from baseline to month 6 in the Phase 2 portion of the trial (prespecified secondary endpoint, difference in least squares mean change from baseline: 6.90, p=0.0365). Furthermore, a post-hoc analysis of the $MACrO_2$ PRO using a 100-point continuous scale similar to QOL-B showed a comparable nominally statistically superior result for the epetraborole arm versus the placebo arm (difference in least squares mean change from baseline: 5.81, p=0.0433). Blinded psychometric analyses incorporating the data from both treatment arms of the Phase 2 study demonstrated strong evidence for the reliability, validity, ability to detect change (responsiveness), and clinically meaningful within-patient changes in both the QOL-B respiratory domain score and the post-hoc $MACrO_2$ total scaled score, suggesting that the scores measured from either PRO may be fit-for-purpose in evaluating response to treatment in patients with treatment-refractory NTM lung disease.

Based on the Phase 2 results and subsequent analyses, we believe epetraborole is the first drug candidate to show statistically favorable patient reported outcome-based improvement in a treatment-refractory MAC lung disease population. We anticipate releasing top-line Phase 3 data from the 97 Phase 3 patients in the second quarter of 2025. If the Phase 3 data are consistent with[LD1] [JP2] the Phase 2 findings, we plan to meet with FDA to discuss potential registrational pathways in TR-MAC lung disease.

Pipeline Programs

We are also studying epetraborole for the treatment of acute melioidosis. We completed enrollment in a 200-patient observational trial (non-epetraborole treatment) in October 2024 and expect to announce topline data in the second half of 2025. These data will inform a potential Phase 2 proof of concept study that is planned to initiate start up activites in the second half of 2025. Melioidosis is a deadly bacterial infection and global bioterrorism threat with a 90-day mortality rate of approximately 50% using standard of care ("SOC") drugs ceftazidime or meropenem. The aim of the program is to meaningfully lower the expected mortality rate by dosing epetraborole on top of SOC.

Beyond epetraborole, we are conducting Investigational New Drug Application (“IND") enabling studies with AN2-502998 (formerly known as AN15368), an investigational, boron-based small molecule in development for the treatment of chronic Chagas disease, and have several research programs targeting the development of novel compounds in oncology and infectious disease based on our boron chemistry platform. In October 2023, we announced an exclusive license agreement with the University of Georgia Research Foundation to advance the development of AN2-502998, originally discovered by researchers at Anacor, in close collaboration with the University of Georgia. AN2-502998 is the only compound of which we are aware to have demonstrated curative activity in preclinical studies across multiple species, including in non-human primates with long-term, naturally acquired chronic infections of diverse *T. cruzi* genetic types. We anticipate initiating a Phase 1 study in 2025. We also anticipate nominating 1 to 2 new development candidates in oncology in 2025.

AN2 is committed to using our boron chemistry platform to address areas of high unmet need in global health, primarily using non-dilutive funding from sources such as public and private agencies and foundations. In September 2023 we received a research grant from the Bill and Melinda Gates Foundation to discover novel, boron containing small molecules for the treatment of tuberculosis and malaria which was renewed in September 2024. In 2022 we received a cost-reimbursement contract award from the National Institute of Allergy and Infectious Diseases (“NIAID”), part of the National Institutes of Health (“NIH”), under which we are able to receive up to $17.8 million in cost reimbursements to advance the development of epetraborole for acute systemic melioidosis and other biothreat pathogens.

Epetraborole Mechanism of Action

Epetraborole is an investigational, boron-containing, orally bioavailable, small molecule inhibitor of bacterial leucyl-tRNA synthetase, or LeuRS, an enzyme that catalyzes the attachment of leucine to transfer RNA, or tRNA, molecules, an essential step in protein synthesis. As shown in Figure A below, epetraborole forms a complex with a $tRNA^{Leu}$ molecule, trapping the terminal ribonucleotide of $tRNA^{Leu}$ in the editing site of the enzyme, to prevent the synthetic site from attaching leucine to $tRNA^{Leu}$ thus shutting down tRNA leucylation and leading to a block in protein synthesis.

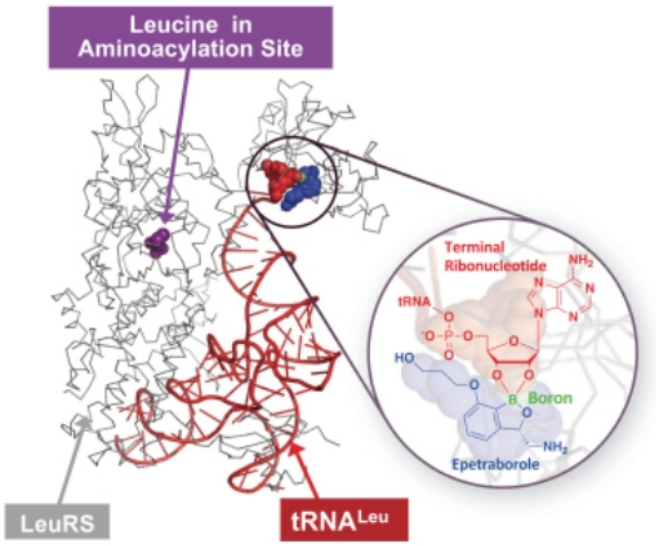

Figure A. Epetraborole is designed to inhibit the protein synthesis enzyme leucyl-tRNA synthetase, or LeuRS, by binding to the terminal adenosine ribose of tRNALeu in the editing site.

As shown in Table 1 below, epetraborole has demonstrated antimicrobial activity against a broad panel of 161 isolates of MAC, with minimum inhibitory concentrations, or MICs, of 0.25 mg/ml to 16 mg/ml. Epetraborole also maintained activity against MAC isolates that are resistant to clarithromycin, a current therapy for NTM treatment regimens.

	MIC (mg/L)		
	Epetraborole	**Clarithromycin**	**Amikacin**
MIC Range	0.25 - 16	0.125 - >64	2 - >64
MIC_{50}	2	1	16
MIC_{90}	4	4	32

Table 1. Antimicrobial activity of epetraborole, clarithromycin and amikacin against 161 isolates of MAC including *M. intracellulare* isolates, *M. avium* isolate, *M. avium* complex isolates, *M. avium* subsp. *hominissuis* isolates, and *M. chimaera* isolates.

Unmet Need in NTM and Market Opportunity for Epetraborole

NTM lung disease is a rare, chronic, and progressive infectious disease caused by bacteria known as mycobacteria that leads to irreversible lung damage and can be fatal. Unlike most bacteria, which replicate quickly and spread outside of cells, mycobacteria replicate slowly and mostly infect alveolar (lung) macrophages and survive within them. Due to the slow growth and survival within macrophages of mycobacteria, the current standard of care for NTM lung infections requires prolonged treatments, often for 18 months or longer, with a combination of three or more antibiotics. Initially, we are focused on developing epetraborole to treat the most common type of NTM, MAC, which accounts for approximately 80% of NTM lung disease in the United States.

There are an estimated 200,000 patients with NTM lung disease in the United States. We believe that many remain underdiagnosed due to lack of clinical suspicion, nonspecific respiratory symptoms, and underlying lung diseases that are frequent in patients with this infection. The prevalence of NTM lung disease is increasing in the United States by an estimated 8% per year. Among the approximately 55,000 patients diagnosed with NTM lung disease in the United States, approximately 44,000 patients have MAC lung disease, and approximately 35% of these patients have treatment-refractory MAC lung disease.

In addition, Japan has some of the highest rates of NTM lung disease in the world. It is estimated that there are 220,000 patients with NTM lung disease and 21,000 patients with treatment-refractory MAC lung disease in Japan.

There is only one FDA-approved therapy for treatment-refractory MAC lung disease: Arikayce, an inhaled liposomal formulation of amikacin. Arikayce is also approved in Japan and certain other countries around the world. Insmed Incorporated reported net sales of Arikayce of approximately $363.7 million in 2024 ($254.8 million in the United States, $87.7 million in Japan, and $21.2 million in Europe and the rest of the world), a 19% increase over 2023. We believe there is significant unmet need for new treatments, particularly in an oral dosage form with differentiated tolerability and mechanism of action. In a clinical trial, the addition of Arikayce to standard of care (SOC) combination antibiotic therapy resulted in the resolution of MAC infection in 29% of patients as compared to 9% for SOC alone (based on an intent to treat population). Arikayce has boxed warnings for risk of increased respiratory adverse reactions, and warnings and precautions including ototoxicity, a known class effect with aminoglycosides, and other safety findings. In its clinical trial, between 20.3% and 33.5% of patients treated with Arikayce discontinued treatment. Other drugs used in combination with Arikayce as a part of a standard-of-care regimen are not approved to treat MAC lung disease and carry numerous safety and tolerability liabilities of their own.

Prior Clinical Experience with Epetraborole

Prior to our clinical development program in NTM lung disease, epetraborole had been administered intravenously or orally as a monotherapy agent to over 200 subjects at a wide range of clinical doses across six Phase 1 and two truncated Phase 2 clinical trials conducted by Anacor and GSK with a focus on gram-negative infections that were unrelated to NTM lung disease, some of which were terminated prior to completion due to clinical resistance observed in a small number of patients in one of the two Phase 2 clinical trials. Epetraborole was not tested by Anacor or GSK in patients with NTM lung disease or in combination with other antimicrobial agents.

Epetraborole Regulatory Exclusivity

As an orphan and QIDP-designated product, if approved in the United States for use in patients with treatment-refractory MAC lung disease, it is possible we could obtain up to 12 years of regulatory exclusivity, independent of any applicable patent protection. If approved in Japan, we believe we could obtain at least eight years of exclusivity, independent of any applicable patent protection that we may acquire.

AN2-502998 Chagas Disease

Chagas disease is caused by the parasite *Trypanosoma cruzi*, which spreads via triatomine bugs (vector), a subspecies of blood-feeding insects more commonly known as “kissing bugs” because they tend to bite people on the face and lips. *T. cruzi* is also transmitted congenitally from infected mothers to their babies, through consumption of contaminated food or beverages, and via blood transfusions and organ transplants. While the disease can progress slowly, chronic infection almost inevitably results in irreparable damage to heart and digestive system tissues. If untreated, infection is lifelong and can be life threatening. Chagas disease kills more people in Latin America than any other infectious disease–including malaria, tuberculosis, and HIV—and is one of the major causes of infection-induced myocarditis or cardiomyopathy worldwide. An estimated 30% of Chagas patients develop chronic and often severe heart disease that leads to premature death.

According to the World Health Organization, approximately 6-7 million people worldwide are estimated to be infected with the parasite *T. cruzi*, mostly in Latin America. An increasing number of cases of Chagas are also being documented in the United States of America and Europe. In the United States, the CDC estimates that there more than 300,000 people infected with *T. cruzi*, most of whom were infected in Chagas-endemic regions in Latin America.

Chagas disease presents in an acute phase (~2 months after infection) and a chronic phase, where the *T. cruzi* parasites are hidden mainly in the heart and digestive muscles. For over 50 years, two nitroheterocyclic compounds, benznidazole and nifurtimox, have been available for treatment of the infection and are FDA approved for use in children, but are rarely used due to their inconsistent efficacy and high frequency of side effects. There are currently no approved therapies to cure the disease once it reaches the chronic phase; however, benznidazole and nifurtimox may be offered to people younger than age 50 because they may help slow the progression of the disease and its most serious complications.

In October 2023, we announced that we signed an exclusive license agreement with the University of Georgia Research Foundation to advance development of AN2-502998 (formerly known as AN15368), a boron-based small molecule therapeutic candidate under development for the treatment of Chagas disease. AN2-502998 was originally discovered by researchers at Anacor, in close collaboration with the University of Georgia, and with grant funding from Wellcome. IND-enabling studies are well underway for this compound. AN2-502998, previously published under AN15368, is the only compound of which we are aware to have demonstrated curative activity in preclinical studies across multiple species, including in non-human primates with long-term, naturally acquired chronic infections of diverse *T. cruzi* genetic types.

Melioidosis

Melioidosis is an urgent unmet global health infectious disease caused by the bacterium *Burkholderia pseudomallei* (*B. pseudomallei*). This bacterium is also documented as a high priority biothreat pathogen by the U.S. CDC. *B. pseudomallei* is endemic to tropical regions of the world with the majority of reported melioidosis cases occurring in South Asia. Melioidosis is contracted from direct contact with *B. pseudomallei* contaminated soil and water and is not transmitted person-to-person. Similar to NTM, *B. pseudomallei* can be an intra-cellular pathogen in host cells including macrophages and other cellular components, an important element in melioidosis disease. The disease can manifest as localized infections causing pain, swelling and ulceration; as pulmonary infections causing cough, chest pain, high fever, and headache; and as blood stream infections causing fever, headache, respiratory distress, and abdominal discomfort. Current treatment generally starts with an intense phase of intravenous antibiotic treatment for a minimum of two weeks. Even with antibiotic treatment, the mortality rate is between 20% and 40%. Without treatment, it is estimated that six to nine out of ten people die. There are an estimated 165,000 cases of melioidosis diagnosed globally each year, mostly outside the United States, although small outbreaks due to bacterial exposure have occurred in the United States and the pathogen was recently discovered in soil and water sampling from the Gulf Coast region of Mississippi. Nonclinical studies conducted by us, Anacor, the U.S. Army Medical Research Institute of Infectious Diseases and Colorado State University indicate that epetraborole has potent activity against *B. pseudomallei.*

In September 2022, we received a cost-reimbursement contract award to receive up to $17.8 million from the NIAID to advance the development of epetraborole for acute systemic melioidosis and additional bacterial biothreat pathogens. The base period contract award is $4.3 million with additional options that, if exercised, would enable us to receive up to $17.8 million in total to support preclinical, Phase 1 studies, and other activities to enable advancement of epetraborole into advanced clinical trials for acute systemic melioidosis. In July 2023, the NIAID exercised one of seven available options under the NIAID contract (No: 75N93022C00059), resulting in an increase in committed contract funding of $0.7 million, for a total of $5.0 million. In May 2024, the NIAID exercised a second contract option, resulting in an increase in committed contract funding of $3.8M, for a total of $8.8M. The project has been funded in whole with nondilutive federal funds from the NIAID, NIH, and the Department of Health and Human Services.

Our work with the NIAID on our melioidosis program has resulted in our partnering with the University of Oxford’s Mahidol Oxford Tropical Medicine Research Unit to conduct a prospective observational study in Thailand and Laos. This trial completed enrollment of 200 patients in October 2024 (NCTC 06089668), and topline data is expected to be available in the second quarter of 2025. We plan to initiate a Phase 2 study in mellioidosis in the second half of 2025. We have also partnered with Colorado State University on preclinical research for our melioidosis program. We believe these partners provide substantial technical and capital resources to advance the mellioidosis program and provide scientific, technical, and material benefits to our NTM lung disease program.

Manufacturing

We do not own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on a limited number of third-party contract manufacturers for all of our required raw materials, drug substance, and finished drug product for our preclinical and nonclinical studies and clinical trials. We currently employ internal resources to manage our third-party manufacturing.

Licensing Agreements

License Agreement with Anacor Pharmaceuticals, Inc.

In November 2019, we entered into a license agreement (the "Anacor Agreement") with Anacor, pursuant to which we obtained a worldwide exclusive, sublicensable license under certain patent rights of Anacor and a non-exclusive license under certain know-how of Anacor to use, develop, manufacture, commercialize, or otherwise exploit certain compounds and products, including epetraborole, for the treatment, diagnosis, or prevention of all human diseases, and a worldwide non-exclusive license under certain chiral synthesis intellectual property rights from GSK for the sole purpose of manufacturing such compounds and products.

We granted Anacor a non-exclusive, sublicensable license to develop, manufacture or use (but not commercialize) licensed products under all intellectual property rights that are both (i) related to the licensed products and (ii) conceived or reduced to practice by us, our affiliates, or our sublicensees. We also granted Anacor a right of first refusal in the event a priority review voucher is issued for a licensed product, and we desire to sell such priority review voucher.

We are obligated to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize (where such regulatory approval is received) epetraborole.

In connection with the execution of the Anacor Agreement, we paid Anacor a non-refundable upfront payment of $2.0 million and granted Anacor shares of Series A redeemable convertible preferred stock. Additionally, we agreed to make further payments to Anacor upon achievement of various development milestones for an aggregate maximum payment of $2.0 million, various commercial and sales threshold milestones for an aggregate maximum payment of $125.0 million, and up to 50% of royalties received under certain sublicensing arrangements. Royalties are subject to certain customary reductions, including lack of patent coverage and generic product entry. We also agreed to pay Anacor non-refundable, non-creditable sales royalties on a tiered marginal royalty rate based on the country's status as a developing or developed country as defined in the license agreement. Sales royalties are a percentage of net sales, as specified in the Anacor Agreement, and range from mid-single digit percentages for developing countries and single to mid-teen percentages for developed countries or the China, Hong Kong, Taiwan, and Macau territories. The sales royalties are required to be paid on a product-by-product and country-by-country basis, until the latest to occur of (i) 15 years following from the date of first commercial sale of a product in such country, (ii) the expiration of all regulatory or data exclusivity for such product in such country, or (iii) the date of the expiration of the last to expire valid claim of a licensed patent covering such product in such country. Currently, the date of the expiration of the last to expire valid claim of a licensed patent covering epetraborole in the licensed territory is June 2028. In addition, Anacor is entitled to certain milestone payments upon a change of control of our company.

On December 3, 2021, we entered into an amendment to the Anacor Agreement, pursuant to which we obtained a worldwide non-exclusive, sublicensable license under certain patent rights of Anacor for the treatment, diagnosis, or prevention of bacterial diseases caused by certain bacterial species, to support the continued manufacture of epetraborole by us.

The Anacor Agreement will expire upon expiration of the last to expire royalty term. Either party may terminate the Anacor Agreement for the other party's material breach following a cure period or immediately upon certain insolvency events relating to the other party.

License Agreement with Brii Biosciences Limited

In November 2019, we entered into a license agreement (the "Brii Biosciences License Agreement") pursuant to which we granted Brii Biosciences an exclusive, perpetual, sublicensable license to research, develop, manufacture, and commercialize certain compounds and products, including epetraborole, in China, Hong Kong, Taiwan, and Macau for the diagnosis, treatment, and prevention of human diseases. Under the terms of the agreement, we licensed the intellectual property rights we licensed under the Anacor Agreement, as they apply in these jurisdictions, to Brii Bioscience. Further, neither we nor Brii Biosciences can develop a competing product that is directed to the same target as a licensed compound during the term of the Brii Biosciences License Agreement.

The collaboration is overseen by a joint steering committee. In the event of a dispute relating to the determination of proof of concept criteria, or licensed products in China, Hong Kong, Taiwan, and Macau for which Brii Biosciences has delivered a proof of concept acceptance notice, Brii Biosciences has the final decision-making authority, subject to certain veto rights of ours. Upon commencing development, Brii Biosciences is obligated to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize at least one licensed product in China, Hong Kong, Taiwan, and Macau.

We did not receive an upfront payment, but we are eligible to receive up to $15.0 million in the aggregate for development and regulatory milestones for each licensed product and up to $150.0 million in the aggregate in commercial milestones upon achieving sales thresholds for each licensed product. We are also entitled to tiered mid-single digit percentage to high-first decile percentage sales-based royalties, subject to certain reductions, including lack of patent coverage and generic product entry. The sales royalties are required to be paid on a product-by-product and region-by-region basis, until the latest to occur of (i) 15 years following the date of first commercial sale of a product, (ii) the expiration of all regulatory or data exclusivity, or (iii) the date of the expiration of the last to expire valid claim of a licensed patent covering the composition of matter or approved use of such product in such region. The last to expire valid claim of a licensed patent covering the composition of matter or approved use of such product in the licensed territory is June 2028.

Global Health Agreement with Adjuvant Global Health Technology Fund

We entered into the Global Health Agreement with Adjuvant Global Health Technology Fund ("Adjuvant") in connection with Adjuvant's investment in November 2019 and March 2021 of an aggregate amount of $12.0 million in our Series A and Series B redeemable convertible preferred stock financings. In connection with such investment, we issued Adjuvant an aggregate of 2,430,714 shares of our redeemable convertible preferred stock in November 2019 and March 2021. Pursuant to the Global Health Agreement, we agreed to support the creation of innovative and affordable drugs to treat disease, through public health programs and private purchasers in low and low-middle income target countries.

Adjuvant's investment supports the development of epetraborole for use in target countries that are melioidosis-endemic, melioidosis at-risk, tuberculosis-endemic, and tuberculosis-at-risk. Under the Global Health Agreement, we are required to comply with certain program-related investment global access commitments. We must use reasonably diligent endeavors to develop epetraborole for melioidosis, tuberculosis, and any other mutually agreed-upon products using non-dilutive funding and we must make them accessible to people in need in target countries on commercially reasonable terms and at a reasonable volume. Upon the occurrence of certain events, including the failure by ourselves to comply with the Global Health Agreement, we must grant Adjuvant a nonexclusive, perpetual, irrevocable, non-terminable, fully-paid up, royalty free license to epetraborole for melioidosis, tuberculosis, and any other mutually agreed-upon products.

Exclusive Patent License Agreement with the University of Georgia Research Foundation, Inc.

In October 2023, we entered into an agreement with the University of Georgia Research Foundation, Inc. ("UGARF") pursuant to which UGARF exclusively licensed to us certain patents and applications that were previously licensed to UGARF by Anacor Pharmaceuticals for us to manufacture and commercialize products for the therapeutic, diagnostic and prophylactic treatment of Chagas disease in humans or animals worldwide. Under the license agreement, we must use commercially reasonable efforts to bring a product in the therapeutic, diagnostic and prophylactic treatment of Chagas disease in humans or animals to market in each territory where there is at least one valid patent claim. We must also use commercially reasonable efforts to attain certain development and sales milestones.

As consideration for the license from UGARF, we paid UGARF an initial license fee in the low five figures. We must also pay a yearly maintenance fee in the low four figures until the initiation of the first clinical trial of the first product covered by the licensed patent claims. Upon achievement of certain development and sales milestones, we are required to make payments of up to approximately $900 million. Should we commercialize any products covered by the licensed patent claims, we will be obligated to pay UGARF annual royalties in the low single digits. Should we sublicense the rights granted under this agreement, we will be obligated to pay UGARF a percentage of the amount received for the sublicense ranging from the mid-single digits to low double digits, depending on the development stage of the first product to enter clinical trials. Should we or a sublicensee transfer or sell to one or more third parties any priority review voucher (or a foreign equivalent) for a product covered by the licensed patent claims, we will be obligated to pay UGARF a percentage of the amount received from such third party ranging from the mid-teens to low double digits, depending on the amount of funding that the third party contributed to develop the product.

The license agreement will terminate on a licensed patent by licensed patent basis until there are no valid claims for a licensed patent. We can terminate the license agreement for convenience on 30 days prior written notice.

Intellectual Property

We strive to protect and enhance our proprietary technology, inventions, and improvements that we consider commercially important to the development of our business, including by seeking, maintaining, and defending U.S. and foreign patent rights. As of December 31, 2024, all of the issued patents in our entire patent portfolio are in-licensed and if our current licensors are not cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any such licensed patent rights, such patent rights could be compromised. The patent positions of pharmaceutical companies are generally uncertain and can involve complex legal, scientific, and factual issues. We cannot predict whether any patent applications we pursue, or any patent applications that we have in-licensed, will issue as patents in any particular jurisdiction, or whether the claims of any issued patents will provide sufficient proprietary protection from competitors.

Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions, and know-how related to our business, including our product candidates, to defend and enforce our intellectual property rights, in particular our patent rights, to preserve the confidentiality of our trade secrets, and to operate without infringing, misappropriating, or violating the valid and enforceable patents and other intellectual property rights of third parties. Our ability to preclude or restrict third parties from making, using, selling, offering to sell, or importing competing molecules to our products may depend on the extent to which we have rights under valid and enforceable patents and trade secrets that cover these activities. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

In addition, the coverage claimed in a patent application may be significantly reduced before a patent is granted, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our products will be protected or remain protectable by enforceable patents. Moreover, any patents that we license or may own in the future may be challenged, circumvented, or invalidated by third parties. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before our product candidate can be commercialized successfully, any related patents may expire or remain in force for only a short period following commercial launch, thereby limiting the protection such patent would afford the applicable product and any competitive advantage such patent may provide. For more information regarding the risks related to our intellectual property, please see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

For any individual patent, the term depends on the applicable law in the country in which the patent is issued. In most countries where we have in-licensed patents and patent applications, including the United States, patents have a term of 20 years from the application filing date or earliest claimed nonprovisional priority date. In the United States, the patent term may be shortened if a patent is terminally disclaimed over another patent that expires earlier. The term of a U.S. patent may also be lengthened by a patent term adjustment that is permitted in order to address administrative delays by the U.S. Patent and Trademark Office ("USPTO") in examining and granting a patent.

In the United States, the term of a patent that covers an FDA-approved drug or biologic may be eligible for patent term extension in order to restore the period of a patent term lost during the premarket FDA regulatory review process. Specifically, the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) permits a patent term extension of up to five years beyond the natural expiration of the patent (but the total patent term, including the extension period, must not exceed 14 years following FDA approval). The patent term extension period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Only one patent applicable to an approved product is eligible for patent term extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. The application for patent term extension must be submitted prior to the expiration of the patent. The USPTO reviews and approves the application for any Patent Term Extension in consultation with the FDA.

The patent portfolio for our epetraborole product candidate is based upon our in-licensed patent portfolio, which includes patents and patent applications directed generally to compositions of matter, pharmaceutical compositions, and methods of treatment. We have exclusively licensed three U.S. patents, along with patents and pending patents in various foreign jurisdictions. We own three pending patent applications for epetraborole. Patents and patent applications, if granted, are expected to expire between 2028 and 2041, without taking potential patent term extensions or patent term adjustments into account.

Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO and other patent offices may be significantly revised before issuance, if granted at all. The in-licensed patents and patent applications for epetraborole are detailed below.

Trade Secrets

We also rely on trade secrets, know-how, confidential information and continuing technological innovation to develop, strengthen and maintain our proprietary position in our field and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. However, trade secrets can be difficult to protect. While we take measures to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. We seek to protect our proprietary information, in part, using confidentiality agreements and invention assignment agreements with our collaborators, employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties. Furthermore, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors and other third parties, or misused by any collaborator to whom we disclose such information. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information regarding the risks related to our intellectual property, please see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our potential competitors have greater financial and technical human resources than we do, as well as greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Accordingly, our potential competitors may be more successful than us in obtaining FDA-approved drugs and achieving widespread market acceptance. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render our product candidates non-competitive or obsolete.

We believe the competitive factors that will affect the development and commercial success of our initial product candidate, epetraborole, if approved, will be convenience of oral dosing, efficacy, safety, and tolerability profile, coverage of drug-resistant bacteria strains, lack of cross-resistance, price, and availability of reimbursement from governmental and other third-party payors.

If approved, epetraborole would compete with Insmed’s Arikayce, which is the only currently approved therapy for patients with treatment refractory MAC lung disease. Other drugs used to treat these patients include generic drugs such as macrolides (clarithromycin and azithromycin), ethambutol, rifabutin, and fluoroquinolones such as levofloxacin, bedaquiline, linezolid, and clofazimine.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, and export and import of drug products. A new drug must be approved by the FDA through the NDA process before it may be legally marketed in the United States. We, along with any third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of certain preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practice regulations and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB"), or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations ("GCPs") to evaluate the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice requirements ("cGMPs") to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- the FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board (DSMB) or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, including clinicaltrials.gov.

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

- ***Phase 1:*** The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- ***Phase 2:*** The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- ***Phase 3:*** The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial regulatory approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Process

The results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act ("PREA"), requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor or the FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Once an NDA has been submitted, the FDA conducts a preliminary review of the application within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act ("PDUFA"), guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCPs.

After the FDA evaluates an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, including additional clinical trials, or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing, which refers to clinical trials designed to further assess a drug's safety and/or effectiveness following NDA approval, and may require additional testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval, including the requirement for 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, which 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 will not approve the NDA without an approved REMS, if required. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational drug. For example, the fast track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. With regard to a fast track product candidate, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review. An NDA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an NDA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Specifically, drugs intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials, and may require that such confirmatory trials be underway prior to granting accelerated approval. Drugs receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for the FDA review or approval will not be shortened.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the disease or condition for which the orphan product has exclusivity or obtain approval for the same product but for a different disease or condition for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a competing product for seven years if a competitor obtains approval of the “same drug,” as defined by the FDA, or if the active moiety of the product candidate is determined to be contained within the competitor’s product for the same disease or condition. In addition, if an orphan designated product receives regulatory approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity.

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws and regulations. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of requirements for post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals;

- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Marketing Exclusivity

Regulatory exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or an NDA submitted under Section 505(b)(2) ("505(b)(2) NDA") submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of non-patent exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to, all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of existing exclusivity or an available patent term if a sponsor conducts clinical trials in children in response to a "written request" from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials, and the FDA's grant of pediatric exclusivity does not require the FDA to approve labeling containing information on pediatric use based on the studies conducted.

Additionally, under the Generating Antibiotics Incentives Now ("GAIN") Act, the FDA may designate a product as a "qualified infectious disease product," or QIDP. In order to receive this designation, a drug must qualify as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens, or (2) a so-called "qualifying pathogen" found on a list of potentially dangerous, drug-resistant organisms established and maintained by the FDA under the law. The FDA interprets QIDP designation to apply to a specific drug product, including a specific dosage form of the product. A sponsor must request such designation before submitting a marketing application, and the FDA will respond to a request for QIDP designation within 60 days of the date the FDA receives the request. The GAIN Act permits the FDA to revoke a QIDP designation only if the request for such designation contained an untrue statement of material fact.

The benefits of QIDP designation include potential eligibility for priority review and Fast Track designation, and an extension by an additional five years of any non-patent regulatory exclusivity period awarded, such as a five-year exclusivity period awarded for a new molecular entity. This extension is in addition to any pediatric exclusivity extension awarded, and the extension will be awarded only to a drug first approved on or after the date of enactment of the GAIN Act. The GAIN Act prohibits the grant of an exclusivity extension where the application is a supplement to an application for which an extension is in effect or has expired, is a subsequent application for a specified change to an approved product, or is an application for a product that does not meet the definition of QIDP based on the uses for which it is ultimately approved.

Tropical Disease Priority Review Voucher Program

In 2007, Congress authorized the FDA to award priority review vouchers ("PRVs"), to sponsors of certain tropical disease product applications. The FDA's Tropical Disease Priority Review Voucher Program is designed to encourage development of new drug and biological products for the prevention and treatment of certain tropical diseases affecting millions of people throughout the world. Under this program, a sponsor who receives an approval for a drug or biologic for the prevention or treatment a tropical disease that meets certain criteria may qualify for a PRV that can be redeemed to receive priority review of a subsequent NDA or Biologics License Application ("BLA"), for a different product. The sponsor of a tropical disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor of an NDA or BLA. The FDCA does not limit the number of times a priority review voucher may be transferred before the voucher is used.

For a product to qualify for a PRV, (i) the sponsor must request approval of the product for the prevention or treatment of a "tropical disease" listed in Section 524 of the FDCA, (ii) the product must otherwise qualify for priority review, and (iii) the product must contain no active ingredient (including any salt or ester of an active ingredient) that has been approved by the FDA in any other NDA or BLA. The Food and Drug Administration Reauthorization Act of 2017 made further changes to the eligibility criteria for receipt of a tropical disease PRV under this program. Specifically, applications submitted after September 30, 2017 must also contain reports of one or more new clinical investigations (other than bioavailability studies) that were essential to the approval of the application and conducted or sponsored by the sponsor. In addition, the applicant must attest that such report(s) were not submitted as part of an application for regulatory approval or licensure by a regulatory authority in India, Brazil, Thailand and certain other countries prior to September 27, 2007.

Other Healthcare Laws

In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback, false claims, and other healthcare fraud and abuse laws, as follows:

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving, or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for, or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal false claims, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

In addition, the civil monetary penalties statute, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program.

The Health Insurance Portability and Accountability Act ("HIPAA") created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" and their respective subcontractors that create, receive, maintain, or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information.

The federal Physician Payments Sunshine Act requires certain manufacturers of 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 report annually to the Centers for Medicare & Medicaid Services ("CMMS"), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals including physician assistants and nurse practitioners, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMMS ownership and investment interests held by physicians and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing information and marketing expenditures or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Violations of any of these laws and other applicable healthcare fraud and abuse laws may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. In the United States, no uniform policy exists for coverage and reimbursement for pharmaceutical products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved.

Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service and the level of coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we are subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain price reporting metrics to the government, such as Medicaid Average Manufacturer Price ("AMP"), and Best Price, Medicare Average Sales Price, the 340B Ceiling Price, and Non-Federal AMP reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries. Compliance with such laws and regulations require significant resources and any findings of non-compliance may have a material adverse effect on our revenues.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In the United States, by way of example, in March 2010, the Affordable Care Act ("ACA") was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented 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 expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Since its enactment, there have been judicial, administrative, executive, and Congressional legislative challenges to certain aspects of the ACA. For example, 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. Thus, the ACA will remain in effect in its current form.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which was temporarily suspended from May 1, 2020 through March 31, 2022. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced payments to several types of Medicare providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the American Rescue Plan Act of 2021, effective January 1, 2024, eliminated the statutory cap on rebate amounts owed by drug manufacturers under the Medicaid Drug Rebate Program ("MDRP"), which was previously capped at 100% of the AMP for a covered outpatient drug.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Most significantly, in August 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued and will continue to issue guidance implementing the IRA. CMS published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on our business and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Data Privacy and Security Laws

As a pharmaceutical company, we are subject to state, federal and foreign laws, including consumer protection laws and regulations, governing the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. For example, in the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws (e.g., the Health Insurance Portability and Accountability Act (“HIPAA”)), and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act) that govern the collection, dissemination, use, protection and other processing of health-related and other personal information currently or could in the future apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act (“CCPA”), and the General Data Protection Regulation (“GDPR”), govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways, thus complicating compliance efforts. Failure to comply with data privacy and security laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, can conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

Japanese Drug Regulation

Being a member of the ICH, Japan has pharmaceutical regulations fundamentally similar to those of the United States and the EU. Clinical trials of medicinal products in Japan must be conducted in accordance with Japanese regulations based on ICH guidelines governing GCP. If the sponsor of the clinical trial is not established within Japan, it must appoint an entity within the country to act as its caretaker who should be authorized to act on the sponsor's behalf. The sponsor must take out a clinical trial insurance policy, and, according to the industry agreement, should put in place a common compensation policy for the injuries from the trial. Prior to the commencement of human clinical studies, the sponsor must complete an evaluation of the safety of the investigative product and submit a clinical trial notification and clinical trial protocol to the authorities in advance, upon agreement of the IRB of the participating institutions. When the authorities do not comment on the notification, the sponsor may proceed with the clinical trial. Any substantial changes to the trial protocol or other information submitted must be cleared by the IRB and notified to the authorities. Medicines used in clinical trials must be manufactured in accordance with GMP.

To market a medicinal product in Japan, we must obtain regulatory approval. To obtain regulatory approval of an investigational medicinal product, we must submit a new drug application. If the product is designed for treating certain "difficult diseases" or those whose patient size is limited, we may be able to obtain designation as an orphan drug product if it demonstrates unique therapeutic value. Separately, the latest amendment to the law introduced separate pathways for (i) truly innovative products with a unique mode of action and (ii) those which will satisfy unmet medical needs.

The evaluation of new drug applications is based on an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy. Once the review organization completes its review, the matter is considered by the advisory committee of experts, and the government grants approval upon positive recommendation from the committee.

The volume and quality of the clinical data are key determinants of the approval decision. Clinical trial data generated overseas is accepted as part of the data package consistent with the ICH recommendation. Typically, a limited dose response clinical trial for Japanese subjects is required to ensure that data are extrapolatable for the Japanese population.

Separate from the approval requirement, it is also mandatory to possess a distribution license of an appropriate class for the manufacturer to commercially distribute the product in Japan. Non-Japanese companies who possess only the product approval may designate an appropriate license holder in Japan to commercially distribute the product, rather than distributing it on its own. The license is valid for five years.

Employees and Human Capital Resources

As of February 28, 2025, we had 22 full-time employees, consisting of research, manufacturing, clinical operations, regulatory, quality, finance, and operational personnel. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate Information

We incorporated in Delaware on February 24, 2017 and launched operations in November 2019. We completed the initial public offering (the "IPO") of our common stock in March 2022, and our common stock is listed on the Nasdaq Global Select Market under the symbol "ANTX." Our principal executive offices are located at 1800 El Camino Real, Suite D, Menlo Park, California, 94027, and our telephone number is (650) 331-9090.

Securities Exchange Act Reports

The Company maintains a website at the following address: https:// www.an2therapeutics.com/. The information on the Company's website is not incorporated by reference in this Annual Report on Form 10-K.

We make available on or through our website reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Securities Exchange Act of 1934, as amended. These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K and amendments to these reports. We make this information available on our website free of charge as soon as reasonably practicable after we electronically file the information available with, or furnish it to, the SEC. The SEC also maintains a website at the following address, through which this information is available: http://www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before you invest in our common stock, you should carefully consider the risks described below together with all of the other information contained in this Annual Report, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. Unless otherwise indicated, references in these risk factors to our business being harmed will include harm to our business, reputation, financial condition, results of operations, and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risk Factors Summary

Investing in shares of our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as more fully described below. The principal factors and uncertainties that make investing in shares of our common stock risky include, among others:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.
- We may not realize the expected benefits from our business restructuring and workforce reduction and we may incur additional costs implementing it or other difficulties.
- We require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce, or altogether cease our current and future product development programs or future commercialization efforts.
- If we do not obtain regulatory approval for and successfully commercialize any of our product candidates, or if we experience significant delays in doing so, we may never become profitable.
- If clinical trials of our product candidates fail to demonstrate safety and/or efficacy of such product candidates to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities and receipt of necessary regulatory approvals could be delayed or prevented.
- We rely on third parties to conduct our preclinical and nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed.
- Even if any of our product candidates receive regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- We operate with a small team and our future success depends on our ability to retain key executives and to attract, retain, and motivate qualified personnel.
- We have identified material weaknesses in our internal control over financial reporting. Due to our failure to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.
- Our rights to develop and commercialize our technology and our other product candidates are subject, in large part, to the terms and conditions of licenses granted to us by others, such as Anacor Pharmaceuticals, Inc. (a wholly owned subsidiary of Pfizer) ("Anacor"). If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to products, technology, or data from third parties, we could lose such rights that are important to our business.

- If we are unable to obtain and maintain patent and other intellectual property protection for our technology, or for our product candidates, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.
- The trading price of our common stock has been and may continue to be volatile.

Risks Related to Our Financial Position and Capital Needs

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We currently have no products approved for commercial sale, have not generated any revenue from the sale of products and have incurred losses in each year since our inception in 2017. In addition, we have limited experience as a company and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry.

On August 8, 2024, we announced topline results from the Phase 2 part of the EBO-301 Phase 2/3 study evaluating epetraborole on top of optimized background regimen (“OBR”) in treatment-refractory MAC lung disease. The Phase 2 part of the study met its primary objective of demonstrating the potential validation of a novel patient-reported outcome (PRO) tool and a higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19). Sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Epetraborole was generally well tolerated in the trial.

Our net loss was $51.3 million and $64.7 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $205.8 million. We have funded our operations to date primarily with proceeds from our underwritten offering (the "Underwritten Offering), our “at-the-market” equity offering program (“ATM Offering”), our IPO, and the sale of our redeemable convertible preferred stock. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical and nonclinical studies, manufacturing, clinical trials, and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We anticipate that our expenses will increase substantially as we:

- continue our ongoing and planned preclinical, nonclinical, and clinical development of our product candidates;
- initiate preclinical and nonclinical studies and clinical trials for product candidates that we may pursue in the future;
- seek to discover and develop future product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- ultimately establish sales, marketing, and distribution infrastructure and scale up external manufacturing capabilities if we move into later-stage clinical trials for, and seek to commercialize, any product candidate for which we may obtain regulatory approval and intend to commercialize on our own;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional clinical, scientific, chemistry, manufacturing and controls personnel;

- add operational, financial, management, and compliance information systems and personnel, including personnel to support our product development and any future commercialization efforts; and
- incur legal, accounting, information systems, and other expenses associated with operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing drugs that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical and nonclinical studies and clinical trials of our product candidates, obtaining regulatory approval, manufacturing, marketing, and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are further delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts, or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced active operations in November 2019, and our operations to date have been largely focused on raising capital, developing epetraborole, broadening our expertise in the development of epetraborole, undertaking preclinical and nonclinical studies, manufacturing clinical trial material, preparing for and initiating clinical trials, and general and administrative operations. As a company, we have not yet demonstrated an ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a commercial product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We have and may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. For example, in August 2024, we announced topline data from the Phase 2 portion of our Phase 2/3 clinical trial evaluating our initial product candidate, epetraborole, in patients with treatment-refractory MAC lung disease. Although the Phase 2 part of the study met its primary objective in demonstrating the potential validation of a novel patient-reported outcome (PRO) tool and a higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19), sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Given these results, we decided to close out the trial and are in the process of planning to unblind the Phase 3 part of the study and meet with the FDA to determine next steps.

In addition, we will need to transition successfully at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We may not realize the expected benefits from our business restructuring and workforce reduction and we may incur additional costs implementing it or other difficulties.

In August 2024, we announced a business restructuring plan and implemented a workforce reduction. The objective of these initiatives was to focus the organization and our resources on product candidates and development compounds to treat Chagas diseases, NTM, melioidosis, other infectious diseases, and oncology while we continue to evaluate the TR-MAC program.

However, the changes to our business strategy and the reduction in workforce may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended workforce reduction, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our development activities, ability to progress our product candidate development, and results of operations or financial condition. As a result of the workforce reduction, we have recognized severance and other charges of $2.2 million as of December 31, 2024, primarily consisting of severance payments and other employee termination-related expenses.

We may also incur other charges, costs, future cash expenditures or impairments not currently contemplated due to events that may occur as a result of, or in connection with, the revised business strategy and workforce reduction. In addition, we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees.

We may also discover that the workforce reduction and cost cutting measures will make it difficult for us to pursue new opportunities and initiatives and require us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. Moreover, there is no assurance we will be successful in our pursuit of any of our new goals. Our failure to successfully accomplish any of the above activities and goals may have a negative impact on our business, financial condition, results of operations and growth prospects.

We require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our current and future product development programs or future commercialization efforts.

We believe that our existing cash, cash equivalents, and investments will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, we will need to obtain substantial additional funding in connection with our continuing operations and planned activities. Our future capital requirements will depend on many factors, including:

- the timing, progress, and results of our ongoing and future clinical trials of our product candidates;
- the costs, timing and outcome of regulatory review of any of our product candidates that may complete or be in the process of completing clinical development;
- the scope, progress, results and costs of identifying, obtaining, and conducting preclinical development, laboratory testing and clinical trials of future product candidates that we may pursue;
- the cost and timetable of manufacturing processes for development, clinical trials and potential commercial use;
- the number and development requirements of future product candidates that we may pursue;
- the amount of funding that we receive under our non-dilutive funding opportunities, including government awards that we may apply for;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any product candidates that receive regulatory approval;
- the pricing and revenue, if any, received from commercial sales of any product candidates that receive regulatory approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or any future commercialization efforts.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or to any of our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or any product candidates, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our development of our product candidates or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have a contractual commitment to develop epetraborole for global health initiatives, which may affect our ability to develop and commercialize epetraborole in certain countries and may impact our intellectual property rights. Our strategy for our global health initiatives depends on receiving non-dilutive funding, and we as a company have limited experience with this strategy.

Under our Global Health Agreement with Adjuvant, we have a contractual commitment to use reasonably diligent endeavors to develop epetraborole and any other mutually agreed-upon products for melioidosis, tuberculosis, and other indications for at-risk developing countries at accessible pricing and at reasonable volume, including selling epetraborole and any other mutually agreed-upon products in certain target countries at or slightly above the cost of sales, so long as we do not sell products at a loss. Under the Global Health Agreement, we made certain commitments to develop epetraborole and any other mutually agreed-upon products and to pursue regulatory strategies and product registrations. If we do not maintain compliance with these and other program-related global access commitments under the Global Health Agreement, Adjuvant may be entitled to repayment for any portion of its investment that is not used for the purposes outlined in the Global Health Agreement. Our obligations under the Global Health Agreement may affect our ability to commercialize epetraborole in certain countries.

Our strategy for developing epetraborole for global health initiatives depends on receiving non-dilutive funding from sources such as public and private agencies and foundations. We, as a company, have limited experience with non-dilutive funding, and we may not be able to obtain additional non-dilutive funding to support our needs to fund our global health initiatives. For example, we cannot be certain that there will be additional awards, contracts, grants or funding sources or solicitations available to support our development efforts, that our other grant applications and funding proposals will be successful, or that we will be able to continue satisfying the award criteria of the NIAID contract award or any grants or funding awarded to us. If we fail to receive additional non-dilutive funding, progress in our global health initiatives may be impaired or delayed.

Risks Related to the Development of Our Product Candidates

If we do not obtain regulatory approval for and successfully commercialize any of our product candidates, or if we experience significant delays in doing so, we may never become profitable.

We currently have no products approved for sale and have historically invested a significant portion of our efforts and financial resources on the development of our initial product candidate, epetraborole, as a treatment for treatment-refractory MAC lung disease. Although we have discontinued our development efforts with respect to epetraborole in the treatment-refractory MAC population studied in the EBO-301 trial until completion of discussions with the FDA to align on potential next steps, our business remains heavily dependent on the successful development, regulatory approval, and, if approved, commercialization of our product candidates. We cannot be certain that any product candidate will receive regulatory approval or will be successfully commercialized even if it receives regulatory approval. The research, development, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of our product candidates are, and will remain, subject to comprehensive regulation by the FDA and other comparable foreign regulatory authorities.

Before obtaining regulatory approvals for the commercial sale of any product candidates, we must demonstrate through preclinical and nonclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage during our nonclinical studies, clinical trials or drug product manufacturing process. These delays or failures could be caused by a variety of factors, including but not limited to, toxicity, safety, tolerability, efficacy, problems with clinical trial enrollment, drug product availability, stability, and impurity issues related to drug product manufacturing. For example, in August 2024, we announced topline data from the Phase 2 portion of EBO-301, our Phase 2/3 clinical trial evaluating epetraborole in patients with treatment-refractory MAC lung disease. Although the Phase 2 part of the study met its primary objective in demonstrating the potential validation of a novel patient-reported outcome (“PRO”) tool and a non-significant, but numerically higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19), sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Given these topline results, we decided to close out the Phase 3 portion of the trial and commence a review of data to help inform further development. Although we believe that to date our ongoing data review supports the continued development of epetraborole in patients with treatment-refractory MAC lung disease, it is possible that we will determine to defer or discontinue development of epetraborole in NTM, whether due to further FDA feedback or otherwise.

Failure to obtain regulatory approval for our product candidates in the United States or other territories will prevent us from commercializing and marketing such product candidates. The success of our product candidates will depend on several additional factors, including:

- successful and timely completion of preclinical and nonclinical studies and requisite clinical trials;
- performing preclinical studies and clinical trials in compliance with the FDA or any comparable regulatory authority requirements;
- receipt of regulatory approvals from applicable regulatory authorities;
- the ability to manufacture sufficient quantity of product for development, clinical trials or potential commercialization;
- obtaining regulatory approvals with labeling for sufficiently broad patient populations and indications, without unduly restrictive distribution limitations or safety warnings, such as black box warnings or a Risk Evaluation and Mitigation Strategies ("REMS") program;
- obtaining and maintaining patent, trademark and trade secret protection, and regulatory exclusivity for our product candidates;
- making and retaining sufficient and reliable arrangements with third parties for manufacturing capabilities;
- launching commercial sales of products, if and when approved;
- acceptance of our therapies, if and when approved, by physicians, patients and third-party payors;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;

- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trademarks, trade secrets and know-how;
- avoiding and defending against third-party infringement, misappropriation or other violation of intellectual property claims;
- maintaining a continued acceptable safety and tolerability profile of our drugs following approval; and
- allowance to proceed with clinical trials under future investigational new drug applications ("INDs"), or under comparable applications submitted outside the United States.

If we do not achieve these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

We may not be successful in our efforts to build a pipeline of product candidates.

A key element of our strategy is to develop our AN2 drug discovery platform, build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of Chagas disease, NTM, melioidosis, other infectious diseases, and in oncology. We may not be able to develop product candidates that are safe and effective for any proposed use. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, as a result of significant safety, tolerability and other negative characteristics or limitations that may prevent successful regulatory approval or limit market acceptance or reimbursements from third-party payors. If we do not successfully develop and commercialize any of our product candidates, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our common stock.

There can be no assurance that any clinical trials we conduct will be sufficient for product approval.

Prior to marketing any product candidate in the United States, we must demonstrate that such product candidate is safe and provide substantial evidence of effectiveness for its intended uses. The FDA has generally interpreted the “substantial evidence” requirements as requiring sponsors to conduct two adequate and well-controlled Phase 3 clinical trials. However, in some circumstances, the FDA may conclude that substantial evidence of efficacy has been demonstrated through the conduct of one adequate and well-controlled clinical trial, plus confirmatory evidence (whether obtained prior to or after such trial). Regardless of the clinical development plans we decide to pursue with respect to our product candidates, there can be no assurance that the FDA will not require additional clinical trials for approval of such product candidates beyond the trials that we currently plan to conduct, even if we successfully complete the trial and believe the results are sufficiently positive.

As a company, we have limited experience designing and conducting clinical trials in the United States or other geographies and may be unable to design and execute a clinical trial to support regulatory approval. In addition, the design and results of our clinical trials may not be sufficient to support approval, since factors such as an inappropriate dosage or flaws in the design of a clinical trial may not become apparent until the clinical trial is in progress or data are available.

There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. For example, in August 2024, we announced topline data from the Phase 2 portion of our Phase 2/3 clinical trial evaluating epetraborole in patients with treatment-refractory MAC lung disease. Although we believe the Phase 2 part of the study met its primary objective in demonstrating the potential validation of a novel patient-reported outcome (PRO) tool and a higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19), sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Given these results, we decided to close the Phase 3 portion of the trial and to commence a review of data to help inform further development.

Although we believe that our ongoing data review to date supports the continued development of epetraborole in patients with treatment-refractory MAC lung disease, it is possible that we will defer or discontinue development of epetraborole in NTM, whether due to further FDA feedback or otherwise. For example, based on the results from the Phase 2 portion of the EBO-301 trial, we submitted an amended statistical analysis plan for the EBO-301 trial selecting the Quality of Life – Bronchiectasis (QOL-B) respiratory domain patient reported outcome (PRO) instrument as the revised primary efficacy endpoint. However, the FDA may not consider the data from the Phase 3 portion of the trial to be clinically meaningful or otherwise supportive for regulatory decision-making purposes, even if the Phase 3 data show a statistically significant outcome with respect to QOL-B.

If clinical trials of our product candidates fail to demonstrate safety and/or efficacy of such product candidates to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may not commercialize, market, promote, or sell any product candidate without obtaining regulatory approval from the FDA or other comparable regulatory authorities, and we may never receive such approvals. It is impossible to predict when or if any of our product candidates will be deemed effective or safe in humans and receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any of our product candidates, we must complete preclinical and nonclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical and nonclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their products. In addition, before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize any of our product candidates, including, but not limited to:

- we may be unable to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- the FDA or other comparable regulatory authorities may disagree as to the design or implementation of our clinical trials, including the selection of primary and secondary endpoints, which may result in changes to our planned clinical trial design and potential target clinical outcomes, or may result in failure to obtain approval altogether;
- regulators, IRBs, or ethics committees may not allow or authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach 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 clinical trial sites;
- we may experience delays in identifying, recruiting and training suitable clinical investigators;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may make changes or amendments to a trial protocol;
- we may select endpoints that require prolonged periods of clinical observation or require extended analysis of the resulting data;
- clinical trial sites may deviate from the trial protocol or drop out of a trial;

- clinical trials for our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- enrollment in clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate, we may fail to recruit suitable patients to participate in a trial, or the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may lack adequate funding to complete a clinical trial, or the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA or other comparable regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with whom we enter into agreements for clinical and commercial supplies;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of such product candidates may be insufficient or inadequate;
- serious adverse events may occur in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

If we are required to conduct additional clinical trials or other testing of any of our product candidates beyond the studies that we currently contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns observed in these trials or tests, we may:

- be delayed in obtaining regulatory approval for our product candidates;
- not obtain regulatory approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, such as black box warnings or a REMS program;
- be subject to additional post-marketing testing requirements; or
- be required to remove the product from the market after obtaining regulatory approval.

We do not know whether any of our preclinical and nonclinical studies or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical and nonclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

We cannot predict whether or when bacteria may develop resistance to any of our antibacterial product candidates, which could affect the revenue potential of our product candidates.

We are developing certain of our product candidates to treat bacterial infections. The bacteria responsible for these infections evolve quickly and may develop antibiotic resistance caused by spontaneous mutations in the genes encoding the cellular target of the antibiotic. In some cases, resistance mechanisms can be transferred within and between bacterial species. Prescription or use of our product candidates, if approved, could depend on the type and rate of resistance of the targeted bacteria. Although we do intend to analyze the potential of emergence of resistance to our product candidates and only select those that we believe have low resistance potential, we cannot predict whether or when bacterial resistance may develop. Such bacterial resistances, if and when identified, could adversely affect the conduct or results of our clinical trials, and could adversely affect the market potential of the product candidate, if approved. The growth of drug-resistant infections in community settings or in countries with poor public health infrastructures, or the potential use of any product candidates outside of controlled hospital settings, could contribute to the rise of resistance.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences following any potential regulatory approval.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates, whether used alone on in combination with other therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or, if such product candidates are approved, result in a more restrictive label and other post-approval requirements. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and growth prospects significantly.

Additional adverse events may emerge (along with additional data further defining previously identified risks) in any ongoing or subsequent clinical trials and there may be unforeseen serious adverse events or side effects that differ from those seen in studies completed to date. It is possible that as we test our product candidates in larger, longer and more extensive clinical programs, or as use of such product candidates becomes more widespread, if they receive regulatory approval, subjects will report illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials. Many times, side effects are only detectable after investigational drugs are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates has unexpected side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business.

Even if we believe our product candidates demonstrate clinical efficacy, any unacceptable adverse side effects or toxicities, when administered in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh potential benefits. We may observe adverse or significant adverse events or drug-drug interactions in future preclinical studies or clinical trial candidates, which could result in the delay or termination of development, prevent regulatory approval or limit market acceptance if ultimately approved. For example, we have observed cases of anemia in patients receiving epetraborole, and though we believe these reported adverse events have not been serious in nature or otherwise suggestive of a material safety issue, consistent imbalances in observed adverse events between active and placebo arms could adversely affect the integrity of a study blind and subsequent trial data.

Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidate may be harmed and our ability to generate revenue through its sale may be delayed or eliminated. Any of these occurrences may significantly harm our business.

Additionally, if any of our product candidates receive regulatory approval, regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication, or the adoption of a REMS program to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by any product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate, or we may decide to suspend marketing or remove a product from the marketplace;
- regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials, including one or more post-marketing research studies;
- we could be sued and held liable for harm caused to patients;
- we may be required to implement REMS, including the creation of a medication guide outlining the risks of such side effects for distribution to patients;
- we could be subject to fines, injunctions or the imposition of criminal or civil penalties;
- we may need to conduct a recall or comparable post-marketing action; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our product candidates and harm our business and results of operations.

If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our effort will focus on potential clinical testing and potential regulatory approval of our current and future product candidates, including the development of AN2-502998, a boron-based small molecule therapeutic candidate for the treatment of Chagas disease, epetraborole for NTM or melioidosis, and other development compounds, an element of our strategy is to discover, develop and commercialize a portfolio of product candidates to treat diseases with high unmet need. We are seeking to do so by utilizing our targeted-design AN2 drug discovery platform, which uses bacterial genomics and state-of-the-art molecular and dynamic models to design active new compounds that target known mechanisms. We focus our clinical development on pathogens, drug targets, and patients with high, unmet medical needs to leverage the development and regulatory paths available for first-in-class or best-in-class therapeutics. Research efforts to identify and develop product candidates require substantial technical, financial, and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties’ patents or other exclusive rights;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted as safe, tolerable and effective by patients, the medical community or third-party payors, if applicable; and
- the FDA or other regulatory authorities may not approve or agree with the intended use of a new product candidate.

If we fail to develop and successfully commercialize our product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities and receipt of necessary regulatory approvals could be delayed or prevented.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials will depend, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate, continue or complete clinical trials of any product candidates that we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials, as required by the FDA or other comparable regulatory authorities. We have limited experience enrolling patients in our clinical trials and cannot predict how successful we will be in enrolling patients in future clinical trials.

Patient enrollment is also affected by other factors including:

- the size and nature of the targeted patient population;
- the severity of the disease under investigation;
- the proximity and availability of clinical trial sites for prospective patients;
- the eligibility criteria for participation in the clinical trial;
- the design of the clinical trial;
- the perceived risks and benefits of the product candidate under study;
- our ability to recruit clinical trial investigators with appropriate experience;
- efforts to facility timely enrollment in clinical trials;
- the availability and efficacy of drugs approved to treat the diseases under study;
- the patient referral practices of physicians;
- our ability to obtain and maintain patient consents;
- the ability to monitor patients adequately during and after treatment; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In particular, we may face delays and difficulties in enrollment in our planned trials of certain of our product candidates because Chagas disease and certain other conditions we may target include rare diseases (i.e., the size of the targeted patient population is small). Because of this, we may experience difficulties in recruiting sufficient patients into certain of our planned clinical trials.

Additionally, other pharmaceutical companies and research institutions targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll any clinical trials. We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. We have experienced enrollment delays in the past. Enrollment delays in these clinical trials may result in further increased development costs for our product candidates, which would reduce the capital we have available to support our current and future product candidates and may result in our need to raise additional capital earlier than planned and could cause the value of our common stock to decline and limit our ability to obtain additional financing.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Interim "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient 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 interim, topline or preliminary data from our clinical trials and preclinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are 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 trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

Interim data from clinical trials that we may complete are further subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

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 value of the particular program, the approvability or commercialization of the particular product candidate or product 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 is 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 product 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 product candidates may be harmed, which could harm our business, financial condition, operating results, growth prospects.

We may conduct clinical trials for our product candidates outside of the United States, and the FDA may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business.

We conduct and may in the future conduct one or more of our clinical trials or a portion of our clinical trials for our product candidates outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the relevant jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it may result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical and nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed.

We are dependent on third parties to conduct our clinical trials, nonclinical studies and preclinical studies. Specifically, we have engaged CROs and consultants to conduct our ongoing and planned preclinical and nonclinical studies and clinical trials, in each case in accordance with trial protocols and regulatory requirements. We also expect to engage CROs for any of our other product candidates that may progress to clinical development. We expect to rely on CROs, as well as other third parties, such as clinical data management organizations, medical institutions, and clinical investigators, to conduct those preclinical and nonclinical studies, clinical trials, and manufacture of our clinical trial material. Currently, we rely on single source third-party research institutions, laboratories, clinical research and manufacturing organizations for research and development. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, or fail to enter into alternative arrangements in a timely manner, our product development activities would be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, we and our CROs are required to comply with regulations and comply with good laboratory practice requirements for the conduct of certain preclinical studies and GCP requirements for clinical trials, which are regulations and guidelines enforced by the FDA, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Similar regulatory requirements apply outside the United States, including the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. Failure to comply with these requirements by us or by third parties can result in FDA refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure or regulatory noncompliance on the part of our distributors could delay clinical development or regulatory approval of our product candidates or commercialization of such product candidates, resulting in additional losses and depriving us of potential product revenue.

Our reliance on single-sourced third parties to manufacture our product candidates increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of the product candidates that we are developing or evaluating, nor are we contemplating plans to do so. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. Our strategy is to continue to outsource all manufacturing of our product candidates and approved products, if any, to third parties.

In order to conduct clinical trials of our product candidates and prepare for commercialization, we will need to identify suitable manufacturers with the capabilities to manufacture our compounds in large quantities in a manner consistent with existing regulations. Our current and future third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities at any other time. If our manufacturers are unable to successfully scale up the manufacture of our current or future product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

We do not currently have any agreements with third-party manufacturers for the long-term commercial supply of any of our product candidates. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of such product candidates or may be unable to do so on acceptable terms.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the failure of such parties to manufacture product candidates according to our specifications or on schedule;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

The facilities used by our third-party manufacturers must be approved for the manufacture of our product candidates by the FDA, or any comparable foreign regulatory authority, pursuant to inspections that will be conducted after we submit an NDA to the FDA, or submit a comparable marketing application to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of our product candidates. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities.

In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

Our product candidates may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

If the third parties that we engage to supply any materials or manufacture product for our preclinical and nonclinical studies and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these studies and trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop such product candidates and compete effectively.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive regulatory approval on a timely and competitive basis.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA or other comparable regulatory agencies and are able to initiate commercialization of any of our product candidates, such product candidates may not achieve market acceptance among physicians, patients and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety, tolerability, efficacy and ease of use of a once-a-day oral dose and other potential advantages compared to alternative treatments;
- the potential and perceived advantages and disadvantages of the product candidates, including cost and clinical benefit relative to alternative treatments;
- the convenience and ease of once-a-day oral administration compared to alternative treatments (e.g., inhaled drug through nebulizer);
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- acceptance by physicians, patients, payor-formularies and treatment facilities and parties responsible for coverage and reimbursement of the product;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- our ability to manufacture the product candidates in sufficient quantities and yields;
- the strength and effectiveness of marketing and distribution support;

- the prevalence and severity of any side effects;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling or an approved REMS;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- whether the product is safe, tolerable and efficacious when used in combination therapy with the current multi-drug standard of care regimen;
- the approval of other new products for the same indications;
- the timing of market introduction of the approved product as well as competitive products; and
- the emergence of bacterial resistance to the product.

If the market size of any product candidate that obtains regulatory approval is significantly smaller than we anticipate, it may not achieve market acceptance or commercial success. This could significantly and negatively impact our business, financial condition, results of operations and growth prospects.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition from major multi-national pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies and generic drug companies with respect to the product candidates that we intend to develop and commercialize. Potential competitors also include academic institutions, government agencies and other public and private research organizations. If our competitors obtain regulatory approval from the FDA or other comparable regulatory authorities for their product candidates more rapidly than we do, it could result in our competitors establishing a strong market position before we are able to enter the market. Our competitors may also succeed in developing, acquiring or licensing technologies and drug products that are more effective, more effectively marketed and sold, or less costly than any product candidates that we may develop, which could render our product candidate non-competitive and obsolete.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and nonclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do as an organization. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, following the announcement of topline data from the Phase 2 portion of our Phase 2/3 clinical trial evaluating epetraborole, we effected a restructuring resulting in the elimination of a significant portion of the workforce and could result in additional unplanned loss of personnel. Continued disruption caused by the transition or by the loss of ongoing services of any qualified scientific and management personnel could delay or prevent the successful development of our current and future product candidates.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop. Our competitors also may obtain approval from the FDA or other comparable regulatory agencies for their product candidates more rapidly than we may obtain approval for ours, which could result in product approval delays if a competitor obtains market exclusivity from the FDA or any comparable regulatory agencies or our competitors establish a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs. Additional drugs may become available on a generic basis over the coming years. If any of our product candidates achieve regulatory approval, we expect that they will be priced at a significant premium over competitive generic drugs.

If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if and when they are approved.

We do not have a sales or marketing infrastructure and have limited experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain regulatory approval, we will need to establish a sales and marketing organization or enter into collaboration, distribution and other marketing arrangements with one or more third parties to commercialize such product candidate. In the United States and other key markets, we intend to build a commercial organization to target areas with the greatest incidence of conditions for which we may at some point obtain regulatory approval and recruit experienced sales, marketing and distribution professionals. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. We may decide to work with regional specialty pharmacies, distributors, and/or multi-national pharmaceutical companies to leverage their commercialization capabilities to commercialize any product candidate for which we may obtain regulatory approval outside of the United States.

If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise to target the areas that we intend to target. If we are unable to establish a sales force and marketing and distribution capabilities, our operating results may be adversely affected.

Factors that may inhibit our efforts to commercialize our drugs on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- unforeseen costs and limitations with regard to setting up a distribution network.

If we are unable to establish our own sales, marketing and distribution capabilities in the United States and other jurisdictions in which any of our product candidates are approved and, instead, enter into arrangements with third parties to perform these services, our revenues and profitability, if any, are likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. We may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates.

Coverage and adequate reimbursement may not be available for any of our product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs, and providers are unlikely to prescribe our drugs, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs and their administration.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue;
- the inability to commercialize any drugs that we may develop; and
- a decline in our share price.

Our product liability insurance coverage may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of any product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our product liability insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with current or future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

There are a variety of risks associated with marketing our product candidates internationally, which could affect our business.

We may seek regulatory approval for our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement landscapes in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended (the “FCPA”), or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

Risks Related to Our Business, Industry and Managing Our Growth

We operate with a small team and our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, financial and business development expertise of Eric Easom, our co-founder, president, and chief executive officer, Sanjay Chanda, Ph.D., our chief development officer, Lucy Day, our chief financial officer, Josh Eizen, J.D., our chief legal and operating officer, Michael R.K. (Dickon) Alley, Ph.D., our co-founder and SVP research fellow and head of biology, Stephen Prior, Ph.D., our chief strategy officer, and Vincent Hernandez, our senior vice president research and head of chemistry, as well as the other members of our research, development, and business teams. Each may terminate employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees.

Our limited personnel and resources may result in greater workloads for our employees compared to those at companies with which we compete for personnel, which may lead to higher levels of employee dissatisfaction and turnover. Recruiting and retaining qualified research, development, and business personnel and, if we progress the development of our product candidates, commercialization, manufacturing, and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of research and development personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Macroeconomic uncertainties have in the past and may continue to adversely impact our business, financial condition, results of operations and growth prospects.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, volatility and disruptions in global markets and supply chains, tariffs, and global conflicts may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, or new tariffs, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. To the extent that macroeconomic uncertainties continue to harm our business, financial condition, results of operations and growth prospects, many of the other risks described in this “Risk Factors” section will be exacerbated.

We have identified material weaknesses in our internal control over financial reporting. Due to our failure to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

Prior to the completion of the IPO, we had been a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the preparation of our financial statements, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses are as follows:

- We did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of resources with (i) an appropriate level of accounting knowledge, experience and training to appropriately analyze, record and disclose accounting matters timely and accurately, and (ii) an appropriate level of knowledge and experience to establish effective processes and controls. Additionally, the lack of a sufficient number of professionals resulted in an inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, insufficient segregation of duties in our finance and accounting functions. This material weakness contributed to the following additional material weaknesses.
- We did not design and maintain effective controls related to the period-end financial reporting process, including designing and maintaining formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures. Additionally, we did not design and maintain controls over the preparation and review of account reconciliations and journal entries, including maintaining appropriate segregation of duties.
- We did not design and maintain effective controls related to the accounting for certain non-routine or complex transactions, including the proper application of U.S. GAAP to such transactions.
- We did not design and maintain effective controls over information technology (“IT”) general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain (i) program change management controls to ensure that information technology program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately, (ii) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate Company personnel, (iii) computer operations controls to ensure that critical batch jobs are monitored and data backups are authorized and monitored, and (iv) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

These IT deficiencies did not result in adjustments to the financial statements. However, the IT deficiencies, when aggregated, could impact maintaining effective segregation of duties, as well as the effectiveness of IT-dependent controls (such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports) that could result in misstatements potentially impacting all financial statement accounts and disclosures that would not be prevented or detected. Accordingly, management has determined the IT deficiencies in the aggregate constitute a material weakness.

We cannot assure you that there will not be future material weaknesses in our internal control over financial reporting in the future. The failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. These identified material weaknesses, or any additional material weaknesses, in our internal control over financial reporting may cause investors to lose confidence in the accuracy and completeness of our financial reports and/or cause the market price of our common stock to decline, and we could be subject to sanctions or investigations by Nasdaq Global Select Market, the SEC or other regulatory authorities. Failure to remediate material weaknesses in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If in the future, we need to expand our research, development, and business capabilities and implement sales, marketing, and distribution capabilities, we may encounter difficulties in managing such growth, which could disrupt our operations.

Although we effected a restructuring to reduce our workforce by approximately 50%, if the development of our product candidates progresses, we may experience growth in the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our product candidates receives regulatory approval, sales, marketing and distribution. To manage any such growth, we will need to implement and improve our managerial, operational, and financial systems, expand our facilities and recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such growth, we may not be able to effectively manage such an expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may also lead to significant costs and may divert our management and research and development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We have in the past and may from time to time in the future evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drug products, intellectual property rights, technologies or businesses, as deemed appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property and drug products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing drug development programs and initiatives in pursuing such a strategic partnership, merger, or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology, or for our product candidates, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by developing and in-licensing intellectual property relating to our product candidates including patent applications in the United States and abroad related to our technology and product candidates that are important to our business. If we or our licensors do not adequately protect the intellectual property we in-license or own, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability. To protect our proprietary positions, we and our licensors file patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive and time-consuming. We and our current licensors and licensees, or any future licensors and licensees, may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We or our current licensors and licensees, or any future licensors or licensees may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection, or fail to continue to prosecute patents relating to our product candidates. Therefore, these and any of our in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our licensors' patents or our patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensors and licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. We cannot predict whether the patent applications we and our licensors or licensees are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. If there are material defects in the form or preparation of our or our licensors' patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how, and we may not be able to prevent such competitors from commercializing such equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and has been the subject of much litigation in recent years. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, recent changes in patent laws in the United States, including the America Invents Act of 2011, and future changes in patent laws in or outside the United States may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights.

We may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in patents or pending patent applications that we in-license or own, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO"), or become involved in opposition, derivation, reexamination, inter partes review, or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates, and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights.

Our licensors' pending and future patent applications and our own pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our or our licensors' patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our in-licensed patents or any patents we may own in the future by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated NDAs to the FDA in which they claim that patents licensed by us or may be owned by us in the future are invalid, unenforceable, and/or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend and/or assert our in-licensed or owned patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court, or other agency with jurisdiction may find our in-licensed patents or any owned patents, should such patents issue in the future, not infringed, invalid and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our in-licensed patents or patents we may own in the future may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any impairment of our intellectual property rights, or our failure to protect our intellectual property rights adequately, could give third parties access to our technology and product candidates and could materially and adversely impact our business, financial condition, results of operations and growth prospects.

Our rights to develop and commercialize our technology and our other product candidates are subject, in large part, to the terms and conditions of licenses granted to us by others, such as Anacor. If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to products, technology, or data from third parties, we could lose such rights that are important to our business.

For certain product candidates, we rely on licenses to certain patent rights and other intellectual property that are important or necessary to the development of these product candidates. For example, we depend on a license agreement from Anacor, a biopharmaceutical company that originally developed epetraborole and is currently a wholly-owned subsidiary of Pfizer. Additionally, we have licensed our rights under the Anacor agreement in China, Hong Kong, Taiwan and Macau to Brii Biosciences.

Anacor has relied upon, our other licensors may have relied upon, and any future licensors may rely upon, third-party companies, consultants or collaborators, or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. We have sublicensed certain patents from Anacor that are owned, maintained and prosecuted by GSK. If third-party companies such as GSK fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize our product candidates that are the subject of such licensed rights could be adversely affected. Further, we rely upon Anacor's compliance with its license agreement with GSK to maintain our sublicense to such patents owned by GSK, and any termination of Anacor's license agreement with GSK could result in us losing our license to epetraborole. Further development and commercialization of our product candidates may require us to enter into additional license or collaboration agreements. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property, or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize our product candidates in the future.

Our license agreement with Anacor, and other intellectual property-related agreements we have entered into and may in the future enter into may impose diligence and other obligations, including payment of milestones and royalties. For example, our license agreement from Anacor requires us to satisfy diligence requirements, including using commercially reasonable efforts to develop and commercialize products. If we fail to comply with our obligations to Anacor or any other or future licensors, those counterparties may have the right to terminate the license agreements, in which event we might not be able to develop, manufacture, or market any product candidate licensed under the agreements, which could materially adversely affect the value of the product candidate being developed under any such agreement and further involve termination of our rights to important intellectual property or technology.

In spite of our efforts, Anacor might conclude, or any other or future licensors might conclude, that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. 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 (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Under our license agreement with Anacor, and any other or future license agreements, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- 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 licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the license agreements involving 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 growth 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 the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be successful in obtaining necessary rights to any product candidates we may develop through acquisitions and in-licenses.

We currently have rights to intellectual property through licenses from third parties, including Anacor, to identify and develop product candidates. We may find it necessary or prudent to obtain licenses from other third-party intellectual property holders in order to avoid infringing these third-party patents. For example, many pharmaceutical companies, biotechnology companies and academic institutions compete with us and may be filing patent applications that are potentially relevant to our business. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to license any intellectual property rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may become involved in lawsuits to protect or enforce our owned or in-licensed patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe, misappropriate or otherwise violate our in-licensed issued patents or other intellectual property rights we may own. To counter such infringement, misappropriation, violation or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against third parties could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their patents, trademarks, copyrights or other intellectual property rights. In addition, our in-licensed patents may become involved in inventorship or priority disputes. Third parties may raise challenges to the validity of certain of our in-licensed patent claims and may in the future raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in derivation, revocation, reexamination, post-grant review ("PGR"), inter partes review ("IPR"), interference proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings challenging any patents that we may own or in-license. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. A third party may also claim that our potential future owned patents or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, invalidate, or render unenforceable, our potential future owned patents or licensed patent rights, allow third parties to commercialize our product candidates 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 In a patent infringement proceeding, there is a risk that a court will decide that a patent we own or in-license is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents are upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our owned or in-licensed patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our owned or in-licensed patents could limit our ability to assert our owned or in-licensed patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, in the future, we expect to rely on trademarks to distinguish our product candidates that are approved for marketing, if any, and if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the third party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to adequately file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors and other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating, otherwise violating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our proprietary chemistry technology without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of antibacterial treatment, including compounds, formulations, treatment methods and synthetic processes that may be applied towards the synthesis of antibiotics. If any such patents of third parties cover our product candidates or technologies, we may not be free to manufacture or market our product candidates as planned.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Third parties may assert claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance.

If we are found to have infringed, misappropriated or otherwise violated any third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing, or commercializing our product candidates. Alternatively, we may be required to obtain a license from such third party in order to use technology and continue developing, manufacturing or marketing product candidates that infringe, misappropriate or otherwise violate such third party's intellectual property rights. However, we may not be able to obtain any such required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We may also be required to pay substantial ongoing royalty or license payments or fees or comply with other unfavorable terms. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. Even if we were to prevail in such a dispute, any litigation regarding our intellectual property rights could be costly and time-consuming and divert the attention of our management and key personnel from our business operations. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. During the course of litigation, there could be public announcements or the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Negative publicity related to a decision by us to initiate such enforcement actions against a customer or former customer, regardless of its accuracy, may adversely impact our other customer relationships or prospective customer relationships, harm our brand and business and could cause the market price of our common stock to decline. Any of the foregoing arising from uncertainty in legal proceedings could materially and adversely impact our business, financial condition, results of operations and growth prospects.

We may be subject to claims by third parties asserting that we or our employees, consultants and advisors have misappropriated their intellectual property rights or claiming ownership of what we regard as our own intellectual property rights.

Many of our employees, consultants and advisors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of third parties in their work for us, we may be subject to claims that we or such employees, consultants and advisors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property rights to execute agreements assigning such intellectual property rights to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own. Further, we may be unsuccessful in executing such agreements with each party who, in fact, conceives, or develops intellectual property that we regard as our own. The assignment of intellectual property may not be self-executing and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our product candidates if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates. Any of the foregoing could have a material adverse impact on our business, financial condition, results of operations and growth prospects.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties who have prior rights to our trademarks or third parties who have prior rights to similar trademarks may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby diluting or impeding our ability to build brand identity and possibly leading to market confusion. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks and may not be able to prevent such third parties from using and marketing any such trademarks.

In addition, any proprietary name we propose to use with any product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively and our business, financial condition, results of operations and growth prospects may be adversely affected.

If we are unable to protect the confidentiality of our proprietary information, know-how and trade secrets, the value of our product candidates could be adversely affected and our business and competitive position would be harmed.

In addition to seeking patent protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these agreements may be inadequate to protect our proprietary and intellectual property rights. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. In addition, we may not be able to obtain adequate remedies for any such breaches. Although we use reasonable efforts to protect this proprietary information and technology, we also cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information, know-how, trade secrets or other proprietary information or each individual who has developed intellectual property on our behalf. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property rights will be effective. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, distracting to management, and time-consuming, and the outcome is unpredictable and varied depending on the jurisdiction. In addition, some courts inside and outside the United States, in countries in which we operate or intend to operate, are less willing, or unwilling, to protect trade secrets, know-how and other proprietary information. Any claims or litigation could cause us to incur significant expenses. Some third parties may be able to sustain the costs of complex litigation more effectively than we can because they have substantially greater resources.

Our employees, consultants, and other parties may unintentionally or willfully disclose our information or technology to competitors and there can be no assurance that the legal protections and precaution taken by us will be adequate to prevent misappropriation of our technology or that competitors will not independently develop technologies equivalent or superior to ours. Trade secrets and know-how can be difficult to protect. Our competitors or other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets. Additionally, competitors could purchase our product candidates and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents we license or may own in the future protecting such candidates might expire before or shortly after such 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 our product candidates. Depending upon the timing, duration, and specifics of any FDA approval of any of our product candidates, one or more of our in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the “Hatch-Waxman Amendments”). The Hatch-Waxman Amendments permit a patent extension term 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. However, we may not be granted an extension 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 patent term extension is less than 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or in-licensed patents and patent applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we or our licensors may not be able to obtain patent protection for certain licensed technology outside 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, even in jurisdictions where we or our licensors do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our in-licensed inventions in all countries outside the United States, even in jurisdictions where our licensors do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Competitors may use our technologies in jurisdictions where we or our licensors have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our preclinical programs. Our in-licensed patents 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 owned or in-licensed intellectual property rights, if pursued and obtained, or the marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and our owned or in-licensed patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 licensors are 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 growth prospects may be adversely affected.

Further, on June 1, 2023, the European Union Patent Package ("EU Patent Package") regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court ("UPC") for litigation involving European patents. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patent applications and patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, results of operations and growth prospects.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale, import, export and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities, with regulations differing from country to country. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We currently do not have any products approved for sale in any jurisdiction. For example, we are not permitted to market any product candidate in the United States until we receive regulatory approval of an NDA from the FDA. We as a company only have limited experience in filing and supporting the applications necessary to gain regulatory approvals and may rely on third-party contract research organizations to assist us in this process.

Approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development. For instance, changes to leadership and the reorganization and rededication of critical resources at the FDA and within similar governmental health authorities across the world, may impact the ability of new products and services from being developed or commercialized in a timely manner. Regulations and requirements vary among jurisdictions, including in Japan and Europe. We have not obtained regulatory approval for any product candidate, and it is possible that our product candidates will never obtain regulatory approval.

We have not sought or obtained regulatory approval for any product candidate, and it is possible that any product candidates we may seek to develop will never obtain regulatory approval. In order to obtain approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the nonclinical or clinical data for a product candidate is promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for product candidates either prior to or post-approval, and it may otherwise object to elements of our clinical development program.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including:

- disagreement with the design, endpoint selection, or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;

- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied may not be sufficiently broad or representative to assure safety in the full populations for which we seek approval;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that our product candidates are safe and effective for the proposed indication;
- disagreement with the interpretation of data from nonclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- requirements for additional nonclinical studies or clinical trials;
- disagreement regarding the formulation, labeling, and/or the specifications we propose for our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies;
- refusals by regulators to accept a submission due to, among other reasons, the content or formatting of the submission; or
- changes in a policies, requirements, or regulations rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage complete the FDA or foreign regulatory approval processes and are successfully commercialized. The lengthy review process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval, which would significantly harm our business, financial condition, results of operations and growth prospects.

Even if we eventually receive approval of an NDA or foreign marketing application for our product candidates, the FDA, or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, often referred to as Phase 4 clinical trials, and the FDA may require the implementation of a REMS, which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Disruptions at the FDA and other government agencies caused by the transition to a new administration with different philosophies, funding shortages, staffing limitations, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including the transition to a new administration, government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and certain Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine operations.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may not be able to obtain or maintain orphan drug designations for any product candidates, and we may be unable to take advantage of the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a diagnosed patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Similar laws exist in Europe and Japan. The European Commission may grant a product orphan medicinal product designation if the product is intended for the treatment, prevention or diagnosis of a life-threatening or very serious condition, with a prevalence in the European Union of not more than five in 10,000 people, and where either no satisfactory method of diagnosis, prevention or treatment of the condition in question exists, or if such method exists that the medicinal product will be of significant benefit to those affected by that condition.

As part of our business strategy, we intend to seek orphan drug designation, where applicable, from the FDA and orphan medicinal product designation from the European Commission; however, we may not be able to obtain or maintain this status for our product candidates. There can be no assurance that any regulatory authority will grant any orphan drug designations.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, it is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

More than one product may be approved by the FDA for the same orphan disease or condition, as long as the products are different drugs, as determined by the FDA. As a result, if any of our product candidates is approved by the FDA and receives orphan drug exclusivity, absent other applicable exclusivities, the FDA can still approve other drugs for use in treating the same indication or disease, which could create a more competitive market for us. The failure to successfully obtain orphan drug exclusivity would adversely affect our business.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same disease or condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same disease or condition if such regulatory authority concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We may attempt to seek accelerated approval in the United States for certain of our product candidates. If we are not able to use that pathway, we may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals, if we receive them at all. In addition, even if an accelerated approval pathway is available to us, it may not lead to expedited approval of our product candidates, or approval at all.

Under the FDCA and implementing regulations, the FDA may grant accelerated approval to a product candidate to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies, upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verity and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, the Food and Drug Omnibus Reform Act of 2022, provided the FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to, among other things, have a confirmatory trial underway prior to such approval being granted.

Prior to seeking accelerated approval for any of our product candidates we intend to seek feedback from the FDA or will otherwise evaluate ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed in these territories. Any approval we are granted for our product candidates in the United States would not assure approval of such product candidates in foreign jurisdictions.

In order to market and sell our product candidates in Japan, the European Union, United Kingdom, other areas of Asia, Australia, and any other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain approval from the FDA. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining approval from the FDA. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and data from clinical studies approved by the FDA may not be accepted by foreign regulatory agencies, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing authorization and may not receive necessary approvals to commercialize our product candidates in any market.

Even if we obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of such product candidates may limit how we manufacture and market the product candidates and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if regulatory approval of any of our product candidates is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including with respect to the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for the product. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials, In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements including ensuring that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP.

Accordingly, assuming we receive regulatory approval for one or more product candidates, we and our contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with the FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted, or suspension or revocation of approvals;
- product seizures or detentions, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA and other regulatory authorities strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet and off-label promotion. For example, any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct or failure to comply with applicable regulatory requirements. Misconduct, errors, or omissions by employees and independent contractors, such as principal investigators, CROs, consultants, commercial partners, and vendors, could include failures to comply with regulations of the FDA and other comparable regulatory authorities, to provide accurate information to such regulators, to comply with manufacturing standards we have established, to comply with healthcare fraud and abuse laws, to report financial information or data accurately, to disclose unauthorized activities to us, or to comply with requirements of government contracts (e.g., the NIAID contract). In particular, sales, marketing, and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing, and promotion, sales commission, customer incentive programs, and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits, and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment, or restructuring of our operations, any of which could adversely affect our ability to operate.

If we successfully commercialize any of our product candidates, failure to comply with our reporting and payment obligations under U.S. governmental pricing programs could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we participate in the Medicaid Drug Rebate Program and/or Medicare Part D, if and when we successfully commercialize a product candidate, we will be required to report certain pricing information for such product candidate to the Centers for Medicare & Medicaid Services, the federal agency that administers the Medicaid and Medicare programs. We may also be required to report pricing information to the U.S. Department of Veterans Affairs. If we become subject to these reporting requirements, we will be liable for errors associated with our submission of pricing data, for failure to report pricing data in a timely manner, and for overcharging government payers, which can result in civil monetary penalties under the Medicaid statute, the federal civil False Claims Act, and other laws and regulations.

Our current and future relationships with healthcare professionals, principal investigators, consultants, customers, and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency and other healthcare laws and regulations, which could expose us to penalties.

Healthcare providers, physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute any product candidates for which we obtain regulatory approval. In addition, we may be subject to physician payment transparency laws and regulations by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons 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, lease or order, or the arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. In addition, 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 monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- HIPAA which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires manufacturers of certain drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare providers (such as nurse practitioners and physicians assistants) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws, 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 and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws requiring the licensure of pharmaceutical sales representatives.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. 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 civil, criminal, and administrative penalties, including, without limitation, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

Changes in healthcare policies, laws, and regulations may impact our ability to obtain approval for, or commercialize our product candidates, if approved.

In the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality, and expand access to care. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives, as well as executive, judicial, and Congressional challenges to existing healthcare laws that have significantly affected, and could continue to significantly affect, the healthcare industry. For example, 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.

On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA") into law, which among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminated 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. In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs and review the relationship between pricing and manufacturer patient programs. For example, the IRA, among other things (i) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions took effect progressively starting in fiscal year 2023. CMS published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

At the state level, legislatures have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure, drug price reporting, and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of regulatory approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Government Downsizing Initiatives Could Adversely Impact FDA Operations, Leading to Potential Delays in Regulatory Review and Approval

Recent government downsizing initiatives, including efforts to reduce the size and scope of federal agencies such as the U.S. Food and Drug Administration ("FDA"), could negatively impact the agency's ability to efficiently review and approve new drug applications. These initiatives may lead to staff reductions, voluntary resignations, and resource constraints that could slow down regulatory processes, including clinical trial oversight, new drug application reviews, and post-market surveillance activities.

In addition, future agency cost-cutting measures, budget reductions, or structural changes remain uncertain and could further disrupt the FDA operations. Any prolonged delays or unpredictability in regulatory timelines may adversely affect our ability to bring our product candidates to market in a timely manner, which could have a material impact on our business, financial condition, and future growth prospects.

Disruptions at the FDA and other government agencies caused by funding shortages, staff reductions or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and/or approve new products can be affected by a variety of factors, including government budget and funding levels, staff reductions, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies such as the EMA, following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs and biologics or modifications to approved drugs or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

If a prolonged government shutdown occurs, or if staffing reductions or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We are subject to privacy and data security laws, rules, regulations, policies, industry standards, and contractual obligations, and our failure to comply with them could harm our business.

We maintain a large quantity of information, including confidential business information and information related to our employees and may maintain or have responsibility for the maintenance of personal information in connection with the conduct of our clinical trials. As such, we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure, and protection of personal information that apply or could apply to our operations or the operations of our partners, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, in particular in relation to health information, which may affect our business and is expected to increase our compliance costs and exposure to liability. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

Compliance with these and any other applicable privacy and data security laws, regulations and other requirements we may be subject to in the future is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with such data protection rules. If we fail to comply with any such laws, regulations or other requirements, we may face significant fines and penalties that could adversely affect our business, financial condition, results of operations or growth prospects. Any failure or perceived failure by us or our third-party processors to comply with these data protection and privacy laws, regulations and requirements could result in significant government enforcement actions, which could include civil, criminal, and administrative penalties, orders requiring that we change our practices, claims for damages, and other liabilities, regulatory investigations and enforcement action, private litigation, significant costs (including in investigating and defending such claims, in remediation measures or changes to our operations), and adverse publicity, any of which could negatively affect our business, financial condition, results of operations and growth prospects. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements.

With laws, regulations, and other obligations relating to privacy and data protection imposing new and relatively burdensome obligations, and with the substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. We are currently in the process of developing and updating our policies and procedures in accordance with requirements under applicable data privacy and protection laws and regulations. We rely on our CROs to ensure compliance with data-privacy regulations that may arise in our trials. Other than our website privacy policy, we do not currently have any formal data privacy policies and procedures in place and have not completed formal assessments of whether we are in compliance with all applicable data privacy laws and regulations. Additionally, if third parties with which we work, such as vendors or service providers, violate applicable laws, rules or regulations or our policies, such violations may also put our or our clinical trial and employee data, including personal data, at risk, and our business, financial condition, results of operations and growth prospects may be adversely affected.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector.

We may engage third parties to sell any approved product candidates outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract, and fraud litigation, reputational harm, and other consequences.

We are also subject to export control, import, and trade sanctions laws and regulations which may restrict or prohibit altogether the provision, sale, or supply of our product candidates to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. Additionally, new or increased tariffs and other changes in U.S. trade policy, including new sanctions, could trigger retaliatory actions by affected countries. Obtaining the necessary export license or other authorization for a particular transaction may be time-consuming and may result in the delay or loss of sales opportunities. Violations of U.S. export control, import, or sanctions laws and regulations can result in significant fines or penalties and possible incarceration for responsible employees and managers.

Risks Related to Ownership of Our Common Stock

Concentration of ownership of our common stock among our existing executive officers, directors, and principal stockholders may prevent new investors from influencing significant corporate decisions and matters submitted to stockholders for approval.

Our executive officers, directors, and current beneficial owners of 5% or more of our capital stock and their respective affiliates beneficially own, in the aggregate, a significant percentage of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, or sale of all or substantially all of our assets, or other significant corporate transactions. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- delaying, deferring, or preventing a change in control;
- entrenching our management and/or the board of directors (the "Board");
- impeding a merger, consolidation, takeover, or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

In addition, some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares were sold in our IPO and recent financings and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or vesting of restricted stock units, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Provisions in our corporate charter documents and under Delaware law, and the adoption of a rights plan, could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition, or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions:

- establish a classified board of directors such that not all members of the Board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our Board;
- limit the manner in which stockholders can remove directors from the Board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our Board to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the “DGCL”), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired more than 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Additionally, in August 2024, we entered into a Rights Agreement, which was previously approved by the Board. In connection with the Rights Agreement, a dividend was declared of one preferred stock purchase right for each share of the Common Stock of the Company outstanding at the Record Date (individually, a “Right” and collectively, the “Rights”).

Each Right entitles the registered holder thereof, after the Rights become exercisable and until August 15, 2025 (or the earlier redemption, exchange or termination of the Rights), to purchase from the Company one one-thousandth of a share of Series A Preferred, of the Company at a price of $6.50 per one one-thousandth of a share of Series A Preferred, subject to adjustment. The Rights will expire on August 15, 2025, subject to the Company's right to extend such date, unless earlier redeemed or exchanged by the Company or terminated. The Rights Agreement could have the effect of discouraging, delaying or preventing a change in management or control over us. While there is no plan to do so at this time, our Board may choose to extend the current Rights Agreement or adopt a new rights agreement in the future.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us or any of our directors, officers, employees, or agents arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws;
- any action or proceeding to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us or any of our directors, officers, employees, or agents that is governed by the internal-affairs doctrine.

Furthermore, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. However, these provisions would 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. In addition, 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. To the extent the exclusive forum provision restricts the courts in which claims arising under the Securities Act may be brought, there is uncertainty as to whether a court would enforce such a provision. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person purchasing or otherwise acquiring or holding any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or with our directors, officers, other employees or agents, or our other stockholders, which may discourage such lawsuits against us and such other persons, or may result in additional expense to a stockholder seeking to bring a claim against us. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, results of operations and growth prospects.

We will have broad discretion in the use of our cash, and may invest or spend our cash in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management will have broad discretion in the application of our cash, and could spend our cash in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our common stock to decline, and delay the development of our pipeline programs as well as commercial preparedness.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future, and accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility or debt securities may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. If we do not pay cash dividends, you could receive a return on your investment in our common stock only if you are able to sell your shares in the future and the market price of our common stock has increased when you sell your shares. As a result, investors seeking cash dividends should not purchase our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2024, we had federal and state net operating loss ("NOLs") carryforwards of approximately $81.3 million and $166.3 million, respectively. Under the Tax Cuts and Jobs Act of 2017 ("the Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), our NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. There is variation in how states have responded and may continue to respond to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future. As a result, our ability to use our pre-change NOLs and tax credits to offset post-change taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

General Risk Factors

The trading price of our common stock has been and may continue to be volatile.

The trading price of our common stock has been subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their shares at or above the price paid for the shares. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report Form 10-K, these factors include:

- the commencement, enrollment or results of our planned and future clinical trials;
- the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the results of our testing and clinical trials;
- unanticipated safety, tolerability or efficacy concerns;
- the loss of any of our key research, development or management personnel;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates;
- changes to our relationships with collaborators, manufacturers, or suppliers;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions;

- the results of our efforts to discover, develop, acquire, or in-license additional product candidates;
- the trading volume of our common stock on the Nasdaq Global Select Market;
- sales of our common stock by us, our executive officers and directors or our stockholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States or other countries where we conduct critical business;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- banking crises or failures; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares of our common stock at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business, or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. We currently have research coverage by a limited number of equity research analysts. Equity research analysts may elect not to continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. We will not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

We are incurring significantly increased costs as a result of operating as a company whose common stock is publicly traded in the United States, and our management is devoting substantial time to new compliance initiatives.

As a public company in the United States, we are incurring significant legal, accounting, and other expenses. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations has increased our legal and financial compliance costs and has made some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur or the timing of such costs.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our senior management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants, and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. Identifying material weaknesses could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Significant disruptions of our or our vendors' information technology systems or cybersecurity incidents could result in significant financial, legal, regulatory, business, and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process, and transmit large amounts of confidential information, including intellectual property, proprietary business information, personal information (including health information), and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and restricted availability of such information. We have also outsourced elements of our operations, including elements of our information technology infrastructure and data processing, to third parties and, as a result, we manage a number of third-party vendors who have access to our computer networks or our information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to other third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks, and exposures, the accessibility and distributed nature of our information technology systems, and the information stored on those systems, make such systems (and the information stored therein) vulnerable to risks that threaten the confidentiality, integrity and availability of these systems and information, including unintentional or malicious, internal, and external attacks on our technology environment. Vulnerabilities can be exploited by diverse threat actors and attack vectors, including through inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Cybersecurity incidents are increasing in their frequency, levels of persistence, sophistication, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states, and others, and utilizing increasingly sophisticated techniques and tools – including AI – that circumvent security controls, evade detection and remove or obfuscate forensic evidence. In addition to access to, loss of or the extraction of information, such attacks could involve the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering/phishing, malicious code embedded in software, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information technology systems or information. In addition, the prevalent use of mobile devices increases the risk of cybersecurity incidents.

Significant disruptions of our or our third-party vendors' or business partners' information technology systems or other similar cybersecurity incidents could adversely affect our business operations and result in the loss, misappropriation, and unauthorized access, use or disclosure of, or the prevention of access to, information, which could result in financial, legal, regulatory, business, and reputational harm to us. In addition, any impact to the confidentiality, integrity or availability of information technology systems and the information stored therein, whether from attacks on our or third-party technology environment or from computer viruses, natural disasters, terrorism, war, telecommunication and electrical failures, or other threats, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from ongoing, completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We cannot ensure that our cybersecurity and data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties with which we work, will prevent breakdowns or breaches in our or their systems or other cybersecurity incidents, including those that cause loss, destruction, unavailability, alteration, dissemination of, or damage, or unauthorized access to, or processing of, our data, including personal information, assets, and other data processed or maintained on our behalf, that could have a material adverse effect upon our reputation, business, financial condition, results of operations and growth prospects.

While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or cybersecurity incidents or that our security measures and processes will be fully implemented, complied with or effective. Nor can we be certain that our third-party vendors or business partners have sufficient measures or processes in place to protect their information technology systems and infrastructure. We, our third-party vendors and business partners are, from time to time, subject to attacks and cybersecurity incidents. While we have not to our knowledge experienced an incident that has had a material impact on our operations or financial results, there is no way of knowing with certainty whether we have experienced any material cybersecurity incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that their systems or information have been compromised. Any event that leads to unauthorized access, use, or disclosure of information, including personal information regarding our patients or employees, or other adverse impact to the availability, integrity or confidentiality of our information technology systems, infrastructure or information, could disrupt our business, harm our reputation, compel us to comply with applicable federal and state breach notification laws and foreign law and contractual equivalents, subject us to time-consuming, distracting, and expensive litigation (including class actions), regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations, and contractual obligations, including those that protect the privacy and security of personal information. It could also result in increased costs to us, including costs to investigate, mitigate and remediate vulnerabilities and incidents, and result in significant legal and financial exposure and reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality, or data security-related legal or other obligations to third parties, or any further cybersecurity incidents, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators, or current and potential partners, to lose trust in us, or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations. Moreover, cybersecurity incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Finally, we cannot guarantee that any costs and liabilities incurred in relation to an incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all. Any of the foregoing could have a material adverse effect on our reputation, business, financial condition, results of operations and growth prospects.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted by SEC rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404, not being required to comply with the auditor requirements to communicate critical audit matters in the auditor's report on the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We have taken advantage of reduced reporting burdens in this Annual Report on Form 10-K. In particular, in this Annual Report on Form 10-K, we have provided only two comparative periods of audited financial statements. We also have not provided all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not "emerging growth companies."

If we fail to adhere to the listing requirements of the Nasdaq Global Select Market our common stock could be delisted.

If we are unable to comply with the listing requirements of the Nasdaq Global Select Market, our stock could be delisted for such failure. If our common stock is delisted from Nasdaq, we could be required to list on the over-the-counter market, which may adversely affect the price and trading liquidity of our common stock. Delisting from the Nasdaq may have other negative results, including the potential loss of confidence in us by employees and partners, the loss of institutional investor interest, fewer business development opportunities and greater difficulty in obtaining financing on favorable terms or at all.

Recent and potential future changes to U.S. and non-U.S. tax laws could materially adversely affect our company.

Existing, new, or future changes in tax laws, regulations, and treaties, or the interpretation thereof, in addition to tax policy initiatives and reforms under consideration in the United States or internationally and other initiatives could have an adverse effect on the taxation of international businesses. Furthermore, countries where we are subject to taxes, including the United States, are independently evaluating their tax policy and we may see significant changes in legislation and regulations concerning taxation. For example, the Tax Act, the CARES Act and the recently enacted IRA made many significant changes to the U.S. tax laws. The Tax Act made broad and complex changes to the Code, including, among other things, reducing the federal corporate tax rate. Additionally, beginning in 2022, the Tax Act required the capitalization of research and experimentation expenses with amortization periods over five and fifteen years pursuant to Code Section 174 ("Section 174"), which could impact our effective tax rate and cash flow. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to any such tax legislation may affect us, and certain aspects of the previously enacted legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the IRA, or any newly enacted federal tax legislation. Other legislative changes could also affect the taxation of holders of our common stock. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we are subject to tax and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden, and cost of tax compliance. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislative changes and the potential tax consequences of investing in or holding our common stock.

Indemnity provisions in various agreements potentially expose us to substantial liability for intellectual property infringement, data protection, and other losses.

Our agreements with third parties may include indemnification provisions under which we agree to indemnify them for losses suffered or incurred as a result of claims of intellectual property infringement or other liabilities relating to or arising from our contractual obligations. Large indemnity payments could harm our business, financial condition, results of operations and growth prospects. Although we normally contractually limit our liability with respect to such obligations, we may still incur substantial liability. Any dispute with a third party with respect to such obligations could have adverse effects on our relationship with that third party and relationships with other existing or new partners, harming our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented cybersecurity risk management practices intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management practices include a cybersecurity incident response plan.

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework ("NIST CSF"). This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Key elements of our cybersecurity risk management practices include but are not limited to:

- risk monitoring and assessments designed to help identify material cybersecurity risks from cybersecurity threats to our critical systems, information, products, services, and our broader enterprise IT environment;
- internal and external IT professionals responsible for managing our (1) cybersecurity risk analysis, (2) security controls, and (3) response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assist with aspects of our security controls;
- cybersecurity awareness training of our employees and senior management; and
- a breach response and cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents.

Although we face risks from cybersecurity threats, no known cybersecurity threats have materially affected or we believe are reasonably likely to materially affect us, including our business, financial condition, results of operations and growth prospects. See "Risk Factors – Significant disruptions of our or our vendors' information technology systems or cybersecurity incidents could result in significant financial, legal, regulatory, business, and reputational harm to us."

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee of our Board (the "Audit Committee") oversight of cybersecurity risks, including oversight of management's implementation of our cybersecurity risk management program. The Audit Committee receives reports at least annually from management on our cybersecurity risks and would be informed of any cybersecurity incidents that management considers to be significant or potentially significant.

Our internal cybersecurity professional reports to our CEO and is responsible for assessing and managing our material risks from cybersecurity threats. The CEO is supported by our Chief Legal Officer in exercising primary oversight for our overall cybersecurity risk management program.

Item 2. Properties.

Our current corporate headquarters are located in Menlo Park, California, where we lease approximately 1,731 square feet of office space pursuant to a lease agreement that commenced in May 2021 and expires in August 2025. We also lease approximately 2,500 additional square feet of adjacent office space pursuant to a lease agreement that commenced in September 2021 and expires in August 2025. Both leases contain two additional 12-month renewal options through August 2027.

We believe that these existing facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

The information in Part IV, Note 7—Commitments and Contingencies—Contingencies is incorporated herein by reference.

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 for Common Stock

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "ANTX" since March 25, 2022. Prior to that date, there was no public trading market for our common stock.

Dividend Policy

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any future determination to declare or pay dividends will be made at the discretion of our Board, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions, capital requirements general business conditions and other factors that our Board may deem relevant. Our future ability to pay cash dividends on our capital stock may be limited by the terms of any future debt or preferred securities.

Stockholders

As of February 28, 2025, we had 29 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of record holders also does not include stockholders whose shares may be held in trust by other entities.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item is incorporated by reference to the definitive proxy statement for our 2025 annual meeting of stockholders (the "Proxy Statement") to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from Public Offering of Common Stock

On March 24, 2022, our registration statement on Form S-1 (File No. 333-263295) was declared effective by the SEC for the IPO of our common stock. Our shares began trading on the Nasdaq Global Select Market on March 25, 2022, and the transaction formally closed on March 29, 2022. In connection with our IPO, we issued and sold an aggregate of 5,290,000 shares of our common stock at a price of $15.00 per share, which included the exercise in full of the underwriters' option to purchase 690,000 additional shares of our common stock at the same price per share, which closed on April 12, 2022. The aggregate gross proceeds for shares sold in our IPO was $79.4 million. After deducting underwriting discounts and commissions and offering costs paid or payable by us of approximately $9.0 million, the net proceeds from the offering were approximately $70.4 million. Upon completion of the sale of the shares of our common stock referenced in this paragraph, our IPO terminated. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors pursuant to our director compensation policy.

There has been no material change in the use of proceeds from our IPO as described in our final prospectus dated March 24, 2022 pursuant to Rule 424(b)(4). We invested the funds received in interest-bearing investment-grade securities and government securities.

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 as of December 31, 2024 and results of operations for the years ended December 31, 2024 and 2023 should be read in conjunction with our financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K ("Form 10-K".) This section of this Form 10-K generally discusses 2024 and 2023 items and year-to-year comparisons between 2024 and 2023. Except as otherwise indicated herein or as the context otherwise requires, references in this Form 10-K to "AN2," the "Company," "we," "us" and "our" refer to AN2 Therapeutics, Inc.

This discussion and analysis and other parts of this Form 10-K contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. See also the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a biopharmaceutical company focused on discovering and developing novel small molecule therapeutics derived from our boron chemistry platform. AN2 has a pipeline of boron-based compounds in development for Chagas disease, non-tuberculous mycobacterial ("NTM") and melioidosis, along with early-stage programs focused on targets in infectious diseases and oncology.

Our lead candidate is epetraborole, which we are studying as a potential once-daily, oral treatment with a novel mechanism of action for patients with non-tuberculous mycobacterial ("NTM") lung disease, a rare, chronic and progressive infectious disease caused by bacteria known as mycobacteria, which leads to irreversible lung damage and can be fatal. Epetraborole is designed to produce broad-spectrum antimycobacterial activity through inhibition of an essential and universal step in bacterial protein synthesis. Its novel mechanism of action is enabled by boron chemistry, our core technology approach. We in-licensed the exclusive worldwide development and commercialization rights for epetraborole from Pfizer Inc. in 2019.

Our lead development target in NTM is treatment-refractory MAC lung disease, a condition with high unmet need where the mycobacterial infection persists despite standard front-line therapies. These patients represent complex cases for treatment, often presenting with structural lung damage, high levels of resistance to background therapies, and persistent symptoms that can significantly degrade quality of life. In 2023, the FDA issued a Guidance for Industry recommending that new potential therapies demonstrate evidence of symptom improvement, measured with patient-reported outcome tools, as the primary endpoint for approval. To date, no drugs have been approved by the FDA based on symptom improvement in a treatment refractory population. The only approved therapy for treatment-refractory MAC lung disease received accelerated approval based on the surrogate endpoint of sputum culture conversion without demonstrating symptom improvement.

On August 8, 2024, we announced topline results from the Phase 2 part of EBO-301, a Phase 2/3 study evaluating epetraborole on top of optimized background regimen ("OBR") in treatment-refractory MAC lung disease, and terminated the Phase 3 portion of the trial with 97 patients enrolled. The Phase 2 part of the study met its primary objective of demonstrating the potential validation of a novel patient-reported outcome (PRO) tool and a higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19). However, sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Epetraborole was generally well tolerated in the trial.

Consistent with the FDA's 2023 Guidance, the primary purpose of the Phase 2 part of the EBO-301 study was to test the validity of multiple patient-reported outcome tools in a treatment refractory population, with the goal of identifying a PRO-based primary endpoint for the Phase 3 portion of the trial. To that end, we recently submitted an amended statistical analysis plan to the FDA selecting the Quality of Life – Bronchiectasis (QOL-B) respiratory domain patient reported outcome (PRO) instrument as the primary efficacy endpoint for the Phase 3 part of the EBO-301 trial. We anticipate releasing top-line Phase 3 data from the 97 Phase 3 patients in the second quarter of 2025. If these Phase 3 data confirm the Phase 2 findings, we plan to meet with the FDA to discuss potential registrational pathways in TR-MAC.

We are also studying epetraborole for the treatment of acute melioidosis. We completed enrollment in a 200-patient observational trial (non-epetraborole treatment) in October 2024 and expect to announce topline data in the second half of 2025. These data will inform a Phase 2 proof of concept study that is planned to initiate start up activities in the second half of 2025. Melioidosis is a deadly bacterial infection and global bioterrorism threat with a 90-day mortality rate of approximately 50% using standard of care (SOC) drugs ceftazidime or meropenem. The aim of the program is to meaningfully lower the expected mortality rate by dosing epetraborole on top of SOC.

Beyond epetraborole, we are conducting Phase-1-enabling studies with AN2-502998 (formerly known as AN15368), an investigational, boron-based small molecule in development for the treatment of chronic Chagas disease, and have several research programs targeting the development of novel compounds in oncology and infectious disease based on our boron chemistry platform. In October 2023, we announced an exclusive license agreement with the University of Georgia Research Foundation to advance the development of AN2-502998, originally discovered by researchers at Anacor, in close collaboration with the University of Georgia. AN2-502998 is the only compound of which we are aware to have demonstrated curative activity in preclinical studies across multiple species, including in non-human primates with long-term, naturally acquired chronic infections of diverse *T. cruzi* genetic types. We anticipate initiating a Phase 1 study in 2025. We also anticipate 1 to 2 new development candidates in oncology in 2025.

In August 2024, we also announced a reduction of approximately 50% of our workforce, which was approved by the Board in connection with our restructuring following discontinuation of the EBO-301 study and to further extend our operating capital. In connection with the workforce reduction, we recognized severance and other charges of $2.2 million, primarily consisting of severance payments and other employee termination-related expenses.

We have incurred significant operating losses to date. We expect that our operating expenses will increase significantly as we advance our current and future product candidates through preclinical, nonclinical, and clinical development, seek regulatory approval, and prepare for and, if approved, proceed to commercialization; acquire, discover, validate, and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; hire additional personnel; and incur costs associated with operating as a public company.

We do not have any products approved for sale and have not generated any revenue since inception. Our net losses were $51.3 million and $64.7 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $205.8 million. We have funded our operations from the sale and issuance of redeemable convertible preferred stock, proceeds from our initial public offering (“IPO”), “at-the-market” equity offering program (“ATM Offering”) and an underwritten offering (the “Underwritten Offering”). From November 2019 through October 2020, we raised an aggregate of $12.0 million from the sale of Series A redeemable convertible preferred stock. In March 2021, we raised an aggregate of $80.0 million from the sale of Series B redeemable convertible preferred stock. In March and April 2022, we completed our IPO, with gross proceeds of $79.4 million and net proceeds of $70.4 million, net of underwriting discounts, commissions and offering expenses. In June 2023, we raised gross proceeds of $20.0 million from the ATM Offering and net proceeds of $19.1 million, after deducting commissions and offering expenses. In August 2023, we raised gross proceeds of $70.0 million from the Underwritten Offering and net proceeds of $65.5 million, after deducting commissions and offering expenses.

As of December 31, 2024, we had cash, cash equivalents and investments of $88.6 million. We believe that our available cash will be sufficient to fund our planned operations through at least twelve months following the date of this Form 10-K.

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time as we can generate revenue from our product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with corporate sources, non-dilutive financing, or through other sources of financing. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

We plan to continue to use third-party service providers, including outside research laboratories, clinical research organizations (“CROs”), and contract manufacturing organizations (“CMOs”), to carry out our preclinical, nonclinical and clinical development, and to manufacture and supply the materials to be used during the development and commercialization of our product candidates. We do not currently have a sales force. If we obtain regulatory approval for any of our product candidates, we intend to hire and deploy a specialty sales force, which will increase our operating costs.

Due to ongoing developments in our business and clinical development and regulatory efforts, among other factors, our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance. For more information on the risks and uncertainties associated with our business and our clinical development and regulatory efforts, among other factors, see “Part I Item 1A—Risk Factors.”

Components of Our Operating Results

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our initial product candidate, epetraborole, and other product candidates. These expenses include fees incurred under arrangements with third parties, including CROs, CMOs, preclinical and nonclinical testing organizations, and academic and non-profit institutions. Research and development expenses also include consulting fees, license fees, payroll and personnel-related expenses, including salaries and bonuses, payroll taxes, employee benefit costs and non-cash stock-based compensation for our research and development employees. We expense both internal and external research and development expenses as they are incurred.

We expect our research and development expenses to increase substantially in the future, as we advance our product candidates into and through clinical trials and pursue regulatory approval. The process of conducting the necessary clinical studies to obtain regulatory approval is costly and time-consuming. Clinical studies generally become larger and more costly to conduct as they advance into later stages and we are required to make estimates for expense accruals related to clinical study expenses, which involve a degree of estimation. The successful development of our product candidates is highly uncertain. The actual probability of success for our product candidates may be affected by a variety of risks and uncertainties associated with drug development, including those set forth in the section of this Form 10-K titled “Risk Factors.” At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of our current or any future product candidates. As a result of these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

General and Administrative Expenses

Our general and administrative expenses consist primarily of payroll and personnel-related expenses, including salaries and bonuses, payroll taxes, employee benefit costs, and non-cash stock-based compensation. Other general and administrative expenses include legal costs of pursuing patent protection of our intellectual property, and professional service fees for auditing, tax, general legal services, and other external consulting and vendor services. We expect our general and administrative expenses to continue to increase in the future, including expenses related to legal, accounting, regulatory, and tax-related services associated with maintaining compliance with requirements of the Nasdaq Global Select Market and the Securities and Exchange Commission ("SEC"), directors and officers liability insurance premiums, and investor relations activities.

Restructuring Charges

Our restructuring charges consist primarily of employee severance payments and other employee termination-related expenses.

Interest Income

Interest income consists of interest income and investment income earned on our cash, cash equivalents, and investments.

Other Income

Other income consists of income associated with foreign currency fluctuations.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table sets forth the significant components of our results of operations:

	Year Ended December 31,			
	2024	2023	Change	% Change
	(in thousands, except percentages)			
Operating Expenses:				
Research and development	$ 40,488	$ 54,871	$ (14,383)	(26%)
General and administrative	14,066	14,764	(698)	(5%)
Restructuring charges	2,234	—	2,234	100%
Total operating expenses	56,788	69,635	(12,847)	(18%)
Loss from operations	(56,788)	(69,635)	12,847	(18%)
Interest income	5,467	4,860	607	12%
Other income	—	43	(43)	(100%)
Net loss	$ (51,321)	$ (64,732)	$ 13,411	(21%)

Research and Development Expenses

Research and development expenses, including related-party research and development expenses, were $40.5 million for the year ended December 31, 2024 compared to $54.9 million for the year ended December 31, 2023. The decrease of $14.4 million was primarily due to decreases in clinical trial costs, chemistry manufacturing and controls ("CMC") expenses, personnel-related expenses, allocated facilities and miscellaneous expenses, licensing fees, and consulting and outside services, partially offset by an increase in preclinical and research expenses. Clinical trials expenses decreased by $5.6 million due to decreased costs associated with the termination of our Phase 2/3 clinical trial in treatment refractory NTM lung disease in August 2024 and completion of our Phase 1 clinical trials in 2023. Costs related to CMC activities decreased by $4.4 million due to completion of certain activities related to epetraborole and the timing of non-dilutive funding expense offsets. Personnel-related costs decreased by $3.3 million due to our restructuring activities. Allocated facilities and miscellaneous expenses decreased by $0.9 million due to recognition of our qualified small business payroll tax credit and our non-dilutive funding expense offset. Licensing fees decreased by $0.2 million and consulting and outside services decreased by $0.1 million. These decreases were partially offset by $0.1 million increase due to the prioritization of certain research programs. During the years ended December 31, 2024 and 2023, a total reimbursement of $3.7 million and $2.5 million, respectively, of operating expenses were recognized related to our funding arrangements.

The following table shows our research and development expenses by type of activity:

	Year Ended December 31,			
	2024	2023	Change	% Change
	(in thousands, except percentages)			
Clinical trials expenses	$ 15,626	$ 21,200	$ (5,574)	(26%)
Personnel-related expenses	13,244	16,561	(3,317)	(20%)
Consulting and outside services	4,707	4,770	(63)	(1%)
Preclinical and research study expenses	3,569	3,517	52	1%
Chemistry manufacturing and controls	2,909	7,316	(4,407)	(60%)
Other expenses	433	1,507	(1,074)	(71%)
Total research and development expenses	$ 40,488	$ 54,871	$ (14,383)	(26%)

General and Administrative Expenses

General and administrative expenses were $14.1 million for the year ended December 31, 2024 compared to $14.8 million for the year ended December 31, 2023. The decrease of $0.7 million was primarily attributable to $0.4 million decrease in professional services expenses, $0.4 million decrease in facilities and miscellaneous expenses and $0.2 million decrease in D&O insurance expenses. These decreases were partially offset by $0.3 million increase in personnel related expenses, primarily related to stock-based compensation expense.

Restructuring Charges

Restructuring charges were $2.2 million for the year ended December 31, 2024 consisting of severance payments and other employee termination-related expenses. We had no restructuring charges for the year ended December 31, 2023.

Interest Income

Interest Income was $5.5 million for the year ended December 31, 2024 compared to $4.9 million for the year ended December 31, 2023. The increase of $0.6 million was due to higher interest rates despite lower cash, cash equivalents and short and long-term investment balances in 2024 as compared to 2023.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses since our inception. For the years ended December 31, 2024 and 2023, we had net losses of $51.3 million and $64.7 million, respectively, and we expect to incur substantial additional losses in future periods. As of December 31, 2024, we had an accumulated deficit of $205.8 million. As of December 31, 2024, we had cash, cash equivalents, short-term investments and long-term investments of $88.6 million. Based on our current business plan, we believe that our available cash will be sufficient to fund our planned operations for at least 12 months following the date of this Form 10-K.

To date, we have funded our operations primarily through our Underwritten Offering, ATM Offering, IPO and private placements of our then existing redeemable convertible preferred stock. In August 2023, we generated approximately $65.5 million from the Underwritten Offering, after deducting commissions and offering expenses. In June 2023, we generated approximately $19.1 million in net proceeds from the ATM Offering, after deducting commissions and offering expenses. In March and April 2022, we generated aggregate net proceeds of approximately $70.4 million from our IPO, after deducting underwriting discounts and commissions and offering expenses. Prior to our IPO, we raised $91.6 million from the issuance of our redeemable convertible preferred stock. Upon the closing of our IPO, all outstanding shares of our then existing redeemable convertible preferred stock were converted into shares of our common stock.

Future Funding Requirements

We do not have any products approved for sale, and we have never generated any revenue from contracts with customers. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval for and commercialize any of our current and future product candidates and we do not know when, or if, those events will occur. Historically, we have incurred operating losses and negative cash flows as a result of ongoing efforts to develop our initial drug product candidate, epetraborole, including conducting ongoing preclinical and nonclinical studies, clinical trials, registration API and drug product materials manufacturing, and providing general and administrative support for these operations. We expect our negative cash flows to increase significantly over the next several years as we advance our product candidates through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, and continue our research and development efforts. We are subject to all the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. Moreover, we expect to continue to incur costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations, as we do not expect positive cash flows from operations in the foreseeable future.

Until we can generate a sufficient amount of revenue from the commercialization of our product candidates, if ever, we expect to finance our future cash needs through public or private equity offerings or debt financings. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our current or future product candidates. If we raise additional funds by issuing equity or convertible debt securities, it could result in dilution to our existing stockholders and increased fixed payment obligations. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Any of the foregoing could significantly harm our business, financial condition, results of operations, and prospects.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements depend on many factors, including:

- the scope, timing, rate of progress, results and costs of our preclinical and nonclinical development activities and clinical trials for our current and future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our drug product candidates;
- the timing of enrollment of any future clinical trials;
- the scope and costs of development and commercial manufacturing activities;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing our product candidates that we successfully commercialize;
- the cost of building a specialty sales force in anticipation of product commercialization;
- the cost of commercialization activities, including building a commercial infrastructure, marketing, sales, and distribution costs;
- our ability to maintain existing, and establish new strategic collaborations, licensing, or other arrangements, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any securities class action, product liability or other lawsuits related to our products;
- the expenses needed to attract, hire, and retain skilled personnel;
- our implementation of operational, financial, and management systems;
- the ongoing costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio; and
- the timing, receipt, and amount of sales of any future approved products, if any.

A change in the outcome of any of these or other variables with respect to the development of any of our current and future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitation on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Adequate funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development programs and clinical trials or we may also be required to terminate rights to future product candidates. If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

See the section titled “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K for additional risks associated with our substantial capital requirements.

Summary Statements of Cash Flows

The following table sets forth a summary of the primary sources and uses of cash:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (49,257)	$ (53,288)
Cash provided by (used in) investing activities	54,589	(43,278)
Cash provided by financing activities	372	84,994
Net increase (decrease) in cash and cash equivalents	$ 5,704	$ (11,572)

Cash Used in Operating Activities

Net cash used in operating activities was $49.3 million for the year ended December 31, 2024, which consisted of a net loss of $51.3 million, primarily due to the use of funds to develop our product candidates, and a net decrease of $3.0 million in our net operating assets and liabilities offset by a net increase of $5.0 million in non-cash charges. The net decrease in our operating assets and liabilities was primarily due to a decrease of $4.5 million in accrued compensation and accrued liabilities due to a decrease in accrued research and development expenses, partially offset by an increase of $0.8 million in prepaid expenses and other current assets, an increase of $0.6 million in accounts payable and an increase of $0.1 million in other current liabilities. The non-cash charges consisted of stock-based compensation expense of $8.3 million, partially offset by net accretion of discounts on investments of $3.3 million.

Net cash used in operating activities was $53.3 million for the year ended December 31, 2023, which consisted of a net loss of $64.7 million, due to the use of funds to develop our initial drug product candidate offset by a net increase of $5.8 million in our net operating assets and liabilities and $5.6 million in non-cash charges. The net increase in our operating assets and liabilities was primarily due to an increase of $6.2 million in accounts payable, accrued compensation and accrued liabilities due to an increase in accrued research and development expenses, and an increase of $0.7 million in other current liabilities, partially offset by a decrease of $1.0 million in prepaid expenses and other current assets and a decrease of $0.1 million in operating lease liabilities. The non-cash charges consisted of stock-based compensation expense of $8.4 million and non-cash operating lease expense of $0.1 million, partially offset by net accretion of discounts on investments of $2.9 million.

Cash Used in Investing Activities

Net cash provided by investing activities was $54.6 million for the year ended December 31, 2024, which primarily consisted of $101.3 million in proceeds from maturities of investments, partially offset by $46.7 million in purchases of investments.

Net cash used in investing activities was $43.3 million for the year ended December 31, 2023, which primarily consisted of $132.2 million in purchases of investments, partially offset by $88.9 million in proceeds from maturities of investments.

Cash Provided by Financing Activities

Net cash provided by financing activities was $0.4 million for the year ended December 31, 2024, which primarily consisted of net proceeds from the issuance of common stock under the ESPP and from the exercises of stock options.

Net cash provided by financing activities was $85.0 million for the year ended December 31, 2023, which primarily consisted of net proceeds from the issuance of common stock in our Underwritten Offering and ATM Offering.

Contractual Obligations and Commitments

In November 2019, we entered into an exclusive worldwide license agreement with Anacor for certain compounds and other intellectual property controlled by Anacor for the treatment, diagnosis, or prevention of disease. In exchange for the worldwide, sublicensable, exclusive right and licenses to develop, manufacture, and commercialize the specified compounds, we paid Anacor a $2.0 million upfront payment in November 2019 and issued Anacor shares of our Series A redeemable convertible preferred stock. We agreed to make further payments to Anacor upon achievement of various development milestones for an aggregate maximum payment of $2.0 million, various commercial and sales threshold milestones for an aggregate maximum payment of $125.0 million, and up to 50% of royalties received under certain sublicensing arrangements. Royalties are subject to certain customary reductions, including lack of patent coverage and generic product entry. We also agreed to pay Anacor sales royalties as a percentage of net sales ranging from single to mid-teens.

We enter into contracts in the normal course of business with third-party contract organizations for preclinical and nonclinical studies and clinical trials, manufacture and supply of our preclinical, nonclinical, clinical trial, and other services and products used for operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Critical Accounting Policies, Significant Judgements, and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgements about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgements and estimates. While our significant accounting policies are described in more detail in Part I, Note 2—Basis of Presentation and Summary of Significant Accounting Policies to our financial statements appearing elsewhere in this Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development

We have entered into various agreements with CMOs and CROs. We record research and development expenses to operations as incurred. Research and development expenses represent costs incurred by us for the discovery and development of our product candidates and the development of our technology and include: internal research and development expense, including employee-related expenses (such as salaries, bonus, benefits, travel and non-cash stock-based compensation expense); external research and development expenses incurred under arrangements with third parties, such as CROs, preclinical testing organizations, CMOs, academic and non-profit institutions and consultants; related-party milestone payments; license fees; and other expenses. Costs to develop our technologies are recorded as research and development expense as incurred.

As part of the process of preparing financial statements, we are required to estimate and accrue expenses. We record the estimated expenses of research and development activities conducted by third-party service providers based upon the estimated level of services performed, progress of the studies, including the receipt of deliverables or completion of agreed-upon events, and contracted costs, within research and development expense in the statements of operations and comprehensive loss. These services include the conduct of clinical, nonclinical and preclinical studies, contract manufacturing activities and consulting services.

Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are deferred and recognized as expense in the period in which the related goods are received or services are realized or utilized. If the costs have been prepaid, this expense reduces the prepaid expenses in the balance sheets, and if not yet invoiced, the costs are included in accrued liabilities in the balance sheets. These costs are a significant component of our research and development expenses. We record amortization of prepaid expenses or accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these third parties. Such payments are evaluated for current or long-term classification based on when they will be realized. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. To date, our estimated accruals have not differed materially from the actual costs.

Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks. We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. 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 may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from external CROs, CMOs and other third-party service providers. To date, we have not experienced material differences between our accrued expenses and actual expenses.

Stock-Based Compensation

We use a fair value-based method to account for all stock-based compensation arrangements with employees and non-employees, which include stock options. The fair value of the option granted is recognized on a straight-line basis over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period, which usually is the vesting period. We account for forfeitures as they occur. In determining fair value of the stock options granted, we use the Black–Scholes option pricing model, which requires the input of subjective assumptions. These assumptions include: the estimated length of time employees will retain their vested stock options before exercising them (expected term), the estimated volatility of our common stock price over the expected term (expected volatility), risk-free interest rate, and expected dividends. See Note 9—Equity Incentive Plan and Stock-Based Compensation to our audited financial statements included elsewhere in this Form 10-K for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2024 and 2023. Changes in the following assumptions can materially affect the estimate of fair value and ultimately how much stock-based compensation expense is recognized; and the resulting change in fair value, if any, is recognized in our statement of operations and comprehensive loss during the period the related services are rendered. These inputs are subjective and generally require significant analysis and judgment to develop.

- Fair Value of Common Stock—See the subsection titled “Common Stock Valuations” below.
- Expected Term—The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.
- Expected Volatility—We use an average historical stock price volatility of a peer group of comparable publicly traded companies in biotechnology and pharmaceutical-related industries to be representative of our expected future stock price volatility, as we have limited trading history for our common stock. For purposes of identifying these peer companies, we consider the industry, therapeutic area, stage of development, size and financial leverage of potential comparable companies. For each grant, we measure historical volatility over a period equivalent to the expected term.
- Risk-Free Interest Rate—The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equivalent to the expected term of the stock award.

- Expected Dividend Rate—We have not paid and do not anticipate paying any dividends in the near future. Accordingly, we estimate the dividend yield to be zero.

For the years ended December 31, 2024 and 2023, there was $0.2 million and an insignificant amount of cash received upon exercise of stock options, respectively.

Indemnification Agreements

We enter into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, we indemnify, hold harmless and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, including in connection with any trade secret, copyright, patent, or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments we could be required to make under these arrangements is not determinable. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the fair value of these agreements is minimal.

We have also agreed to indemnify our directors and officers for certain events or occurrences while the director or officer is, or was serving, at our request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service. The maximum potential amount of future payments we could be required to make under these indemnification agreements is not specified in the agreements; however, we have director and officer insurance coverage that reduces our exposure and enables us to recover a portion of any future amounts paid.

Recent Accounting Pronouncements

See the section "Recently Adopted Accounting Pronouncements" in Note 2 to the Notes to Financial Statements in Part IV, Item 15 of this Annual Report on Form 10-K.

JOBS Act Accounting Election

The JOBS Act permits an "emerging growth company" or "EGC" such as us to delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an EGC or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, the information we provide may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

In addition, we intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We will remain an EGC until the earliest to occur of: (1) the last day of our first fiscal year in which we have total annual revenues of more than $1.235 billion; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three- year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our IPO.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and investments of $88.6 million as of December 31, 2024, which consisted primarily of money market funds and marketable securities, largely composed of investment grade, short and long- term fixed income securities and government securities.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash, cash equivalents, and investments in accordance with our Board-approved investment policy.

Our investments are subject to interest rate risk and could fall in value if market interest rates increase. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our financial statements. We do not believe that inflation, interest rate changes or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Foreign Currency Risk

A small portion of our expenses are denominated in foreign currencies. Future fluctuations in the value of the U.S. Dollar may affect the price we pay for services performed outside the United States. We were not exposed to material foreign currency risk during the year ended December 31, 2024.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and operating costs including clinical trial, non-clinical study and manufacturing costs. We believe that inflation has not had a material effect on our financial statements included elsewhere in this Annual Report on Form 10-K.

Item 8. Financial Statements and Supplementary Data.

The financial statements and related financial statement schedules required to be filed are listed in Part IV, Item 15 of this Annual Report on Form 10-K.

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 Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the period covered by this Form 10-K.

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 rules and forms of the SEC. 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 CEO and CFO, 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.

Our CEO and CFO have concluded that as of December 31, 2024, our disclosure controls and procedures were not effective due to material weaknesses in internal control over financial reporting, as described below.

Notwithstanding the identified material weaknesses, management, including our CEO and CFO, have determined, based on the procedures we have performed, that the financial statements included in this Annual Report on Form 10-K were prepared in accordance with U.S. GAAP.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Management has evaluated the effectiveness of our internal control over financial reporting as of December 31, 2024 using the criteria set forth in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation, management has concluded that as of December 31, 2024, our internal control over financial reporting was not effective due to material weaknesses in internal control over financial reporting, as described below.

During the course of preparing for our March 2022 IPO, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of its annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified were as follows, and continue to exist as of December 31, 2024:

- We did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of resources with (i) an appropriate level of accounting knowledge, experience and training to appropriately analyze, record and disclose accounting matters timely and accurately, and (ii) an appropriate level of knowledge and experience to establish effective processes and controls. Additionally, the lack of a sufficient number of professionals resulted in an inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, insufficient segregation of duties in our finance and accounting functions. This material weakness contributed to the following additional material weaknesses.
- We did not design and maintain effective controls related to the period-end financial reporting process, including designing and maintaining formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures. Additionally, we did not design and maintain controls over the preparation and review of account reconciliations and journal entries, including maintaining appropriate segregation of duties.

The above material weaknesses resulted in adjustments to accrued expenses balances, which were recorded prior to the issuance of the financial statements, as of and for the years ended December 31, 2019 and 2020. Additionally, these material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

- We did not design and maintain effective controls over information technology (“IT”) general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain (i) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately, (ii) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate Company personnel, (iii) computer operations controls to ensure that critical batch jobs are monitored and data backups are authorized and monitored, and (iv) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

These IT deficiencies did not result in adjustments to the financial statements. However, the IT deficiencies, when aggregated, could impact maintaining effective segregation of duties, as well as the effectiveness of IT-dependent controls (such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports) that could result in misstatements potentially impacting all financial statement accounts and disclosures that would not be prevented or detected. Accordingly, management has determined the IT deficiencies in the aggregate constitute a material weakness.

Attestation Report of Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report from our independent registered public accounting firm on our internal control over financial reporting due to an exemption established by the JOBS Act for EGCs.

Remediation of Prior Material Weakness

Management previously identified a material weakness in the design and operating effectiveness of controls related to the accounting for certain non-routine or complex transactions, including the proper application of U.S. GAAP to such transactions. As of September 30, 2023, we finalized the design and were validating the effectiveness of controls to account for and disclose complex transactions. As of December 31, 2023, we validated the effectiveness of controls to account for and disclose complex transactions. The applicable controls have been in operation for a sufficient period of time, and management has concluded, through testing, that these controls are operating effectively. Accordingly, the material weakness associated with the accounting for certain non-routine or complex transactions, including the proper application of U.S. GAAP, was remediated as of December 31, 2023.

Remediation Plan for Remaining Material Weaknesses

The Company is committed to remediating the material weaknesses in our internal control over financial reporting. We have implemented measures designed to improve our internal control over financial reporting to remediate these material weaknesses, and are refining the design and validating the effectiveness of these controls, including (i) ongoing hiring of additional accounting personnel; (ii) designing and implementing internal controls in our financial control environment, including establishing formal accounting policies and procedures and financial reporting controls; and (iii) implementing an accounting system upgrade with IT controls to ensure appropriate and restricted access to our accounting applications, programs, and data, including upgrading of our accounting system.

Other than the material weakness associated with the accounting for certain non-route or complex transactions, including the proper application of U.S. GAAP, which has been remediated, the remaining material weaknesses will not be considered remediated until the design requirements described above have been finalized, and the applicable controls have operated for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Accordingly, the material weaknesses related to lack of sufficient resources, insufficient segregation of duties, lack of designing and maintaining formal accounting policies, procedures and controls and lack of designing and maintaining effective controls over IT, were not remediated as of December 31, 2024.

Limitations on the Effectiveness of Controls

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

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 year ended December 31, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the fourth quarter of 2024, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K.

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 is incorporated by reference to the Proxy Statement to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

We have adopted insider trading policies and procedures governing the purchase, sale and other dispositions of our securities by directors, officers and employees that are designed to promote compliance with insider trading laws, rules and regulations, and applicable Nasdaq listing standards, as well as procedures designed to further the foregoing purposes. A copy of our insider trading policy is filed with this Annual Report on Form 10-K as Exhibit 19.1.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the Proxy Statement to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to the Proxy Statement to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference to the Proxy Statement to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to the Proxy Statement to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as a part of this Annual Report:

(1) Financial Statements:

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits:

The list of exhibits filed with this Annual Report on Form 10-K is set forth in the Exhibit Index preceding the signature page and is incorporated herein by reference or filed with this Annual Report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

Item 16. Form 10-K Summary.

None.

Exhibit Index

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-41331	3.1	June 24 2025
3.2	Amended and Restated Bylaws.	S-1	333-263295	3.4	March 4, 2022
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock of AN2 Therapeutics, Inc. filed with the Secretary of State of the State of Delaware on August 15, 2024.	8-K	001-41331	3.1	August 19, 2024
4.1	Form of Common Stock Certificate.	S-1	333-263295	4.1	March 21, 2022
4.2	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated March 5, 2021.	S-1	333-263295	4.2	March 4, 2022
4.3	Description of Securities	10-K	001-41331	4.3	March 29, 2023
4.4	Rights Agreement, dated as of August 15, 2024, between AN2 Therapeutics, Inc. and Equiniti Trust Company, LLC, which includes Form of Certificate of Designations of Series A Junior Participating Preferred Stock as Exhibit A, the Form of Rights Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Stock as Exhibit C.	8-K	001-41331	4.1	August 19, 2024
10.1#	AN2 Therapeutics, Inc. 2017 Equity Incentive Plan, as amended.	S-1	333-263295	10.1	March 4, 2022
10.2#	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise and Early Exercise Stock Purchase Agreement under the AN2 Therapeutics, Inc. 2017 Equity Incentive Plan.	S-1	333-263295	10.2	March 4, 2022
10.3#	AN2 Therapeutics, Inc. 2022 Equity Incentive Plan	10-K	001-41331	10.3	March 29, 2024
10.4#	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the AN2 Therapeutics, Inc. 2022 Equity Incentive Plan.	S-1	333-263295	10.4	March 4, 2022
10.5#	Form of Restricted Stock Unit Grant Notice and Award Agreement under the AN2 Therapeutics, Inc. 2022 Equity Incentive Plan.	10-K	001-41331	10.5	March 29, 2024
10.6#	AN2 Therapeutics, Inc 1022 Employee Stock Purchase Plan.	10-K	001-41331	10.6	March 29, 2024
10.7#	AN2 Therapeutics, Inc. 2022 Non-Employee Director Compensation Policy.	S-1	333-263295	10.7	March 4, 2022
10.8#	AN2 Therapeutics, Inc. Officer Severance Plan.	S-1	333-263295	10.8	March 4, 2022
10.9#	Form of Indemnity Agreement by and between the Registrant and its directors and executive officers.	S-1	333-263295	10.9	March 4, 2022
10.10#	Offer Letter by and between the Registrant and Eric Easom, dated November 19, 2019.	S-1	333-263295	10.10	March 4, 2022
10.11#	Offer Letter by and between the Registrant and Lucy Day, dated November 19, 2019.	S-1	333-263295	10.11	March 4, 2022
10.12#	Offer Letter by and between the Registrant and Sanjay Chanda, dated November 19, 2019.	S-1	333-263295	10.12	March 4, 2022
10.13‡	License Agreement by and between the Registrant and Anacor Pharmaceuticals, Inc., dated November 20, 2019, as amended on December 3, 2021.	S-1	333-263295	10.13	March 4, 2022
10.14‡	License Agreement by and between the Registrant and Brii Biosciences Limited, dated November 20, 2019.	S-1	333-263295	10.14	March 4, 2022
10.15	Amended and Restated Global Health Agreement by and among the Registrant, Adjuvant Global Health Technology Fund L.P., and Adjuvant Global Health Technology Fund DE L.P., dated March 5, 2021.	S-1	333-263295	10.15	March 4, 2022

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.16#	Offer Letter by and between the Registrant and Joshua Eizen, dated September 19, 2022.	10-Q	001-41331	10.1	November 9, 2022
10.17#*	AN2 Therapeutics, Inc. 2024 Amended Non-Employee Director Compensation Policy				
10.18‡*	Exclusive Patent License Agreement, dated October 10, 2023, by and between the Registrant and the University of Georgia Research Foundation, Inc				
19.1*	AN2 Therapeutics, Inc. 2022 Insider Trading Policy				
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.				
24.1*	Power of Attorney (incorporated by reference to the signature page to this Annual Report on Form 10-K.)				
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.				
97.1	Compensation Recovery Policy.	10-K	001-41331	97.1	March 29, 2024
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents**				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.

# Indicates management contract or compensatory plan.

‡ Portions of this exhibit (indicated by [*]) have been omitted because the registrant has determined that the information is both not material and is the type that the registrant treats as private or confidential.

** The following materials are formatted in Inline XBRL (Extensible Business Reporting Language): (i) the cover page; (ii) the Balance Sheets as of December 31, 2024 and 2023; (iii) the Statements of Operations and Comprehensive Loss for the years ended December 31, 2024 and 2023; (iv) the Statements of Stockholders' Equity for the years ended December 31, 2024 and 2023; (vi) the Statements of Cash Flows for the years ended December 31, 2024 and 2023; (vii) Notes to Financial Statements tagged as blocks of text.

† The certification attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Annual Report is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on March 25, 2025**.**

AN2 Therapeutics, Inc.

By: /s/ Eric Easom
Eric Easom
Chief Executive Officer and Director
(Principal Executive Officer)

By: /s/ Lucy O. Day
Lucy O. Day
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Eric Easom and Lucy O. Day, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign 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 requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Eric Easom **Eric Easom**	Chief Executive Officer, Chair and Director (Principal Executive Officer)	March 25, 2025
/s/ Lucy O. Day **Lucy O. Day**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 25, 2025
/s/ Maggie FitzPatrick **Maggie FItzPatrick**	Lead Independent Director	March 25, 2025
/s/ Kabeer Aziz **Kabeer Aziz**	Director	March 25, 2025
/s/ Gilbert L. Marks **Gilbert L. Marks**	Director	March 25, 2025
/s/ Patricia (Patty) Martin **Patricia (Patty) Martin**	Director	March 25, 2025
/s/ Rob Readnour **Rob Readnour**	Director	March 25, 2025
/s/ Melvin Spigelman **Melvin Spigelman**	Director	March 25, 2025
/s/ Stephanie Wong **Stephanie Wong**	Director	March 25, 2025
/s/ Joseph Zakrzewski **Joseph Zakrzewski**	Director	March 25, 2025

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of AN2 Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of AN2 Therapeutics, Inc. (the "Company") as of December 31, 2024 and 2023, and the related statements of operations and comprehensive loss, of stockholders' equity and of cash flows for the years then ended, including 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 December 31, 2024 and 2023, and the results of its operations and its cash flows for 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 of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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.

Emphasis of Matter

As discussed in Note 2 to the financial statements, the Company will require additional financing to fund future operations. Management's plans in regard to this matter are also described in Note 2.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 25, 2025

We have served as the Company's auditor since 2021, which includes periods before the Company became subject to SEC reporting requirements.

AN2 THERAPEUTICS, INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 21,351	$ 15,647
Short-term investments	62,267	91,648
Prepaid expenses and other current assets	2,644	3,212
Total current assets	86,262	110,507
Long-term investments	5,021	27,194
Other assets, long-term	804	1,043
Total assets	$ 92,087	$ 138,744
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,317	$ 2,676
Accrued compensation	1,676	4,018
Accrued liabilities	4,454	6,681
Other current liabilities	791	666
Options subject to repurchase, short-term	—	2
Total liabilities	10,238	14,043
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized at December 31, 2024 and December 31, 2023, respectively; no shares issued and outstanding at December 31, 2024 and December 31, 2023	—	—
Common stock, $0.00001 par value; 500,000,000 shares authorized at December 31, 2024 and December 31, 2023; 29,919,634 and 29,741,445 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	287,594	278,881
Accumulated other comprehensive gain	31	275
Accumulated deficit	(205,776)	(154,455)
Total stockholders' equity	81,849	124,701
Total liabilities and stockholders' equity	$ 92,087	$ 138,744

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

AN2 THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 40,488	$ 54,871
General and administrative	14,066	14,764
Restructuring charges	2,234	—
Total operating expenses	56,788	69,635
Loss from operations	(56,788)	(69,635)
Interest income	5,467	4,860
Other income	—	43
Net loss	(51,321)	(64,732)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.72)	$ (2.74)
Weighted-average number of shares used in computing net loss per share, basic and diluted	29,828,227	23,600,107
Other comprehensive loss:		
Unrealized (loss) gain on investments	(244)	649
Comprehensive loss	$ (51,565)	$ (64,083)

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

AN2 THERAPEUTICS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share and per share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2022	19,402,658	$ —	$ 185,469	$ (374)	$ (89,723)	$ 95,372
Issuances of common stock in the "at the market" offering, net of underwriter's commission and offering costs of $0.9 million	2,502,000	—	19,050	—	—	19,050
Issuances of common stock in the Underwritten Offering, net of underwriter's commission and offering costs of $4.5 million	7,777,778	—	65,479	—	—	65,479
Issuance of common stock under the ESPP	44,009	—	366	—	—	366
Issuance of common stock upon exercise of stock options	15,000	—	99	—	—	99
Vesting of early exercised stock options	—	—	6	—	—	6
Stock-based compensation	—	—	8,412	—	—	8,412
Unrealized gain on available-for-sale investments	—	—	—	649	—	649
Net loss	—	—	—	—	(64,732)	(64,732)
Balances at December 31, 2023	29,741,445	—	278,881	275	(154,455)	124,701
Issuance of common stock under the ESPP	70,700	—	147	—	—	147
Issuance of common stock upon exercise of stock options	28,930	—	225	—	—	225
Vesting of early exercised stock options	—	—	3	—	—	3
Issuance of common stock upon release of restricted stock units	38,556	—	—	—	—	—
Issuance of common stock upon release of restricted stock awards	40,003	—	—	—	—	—
Stock-based compensation	—	—	8,338	—	—	8,338
Unrealized loss on available-for-sale investments	—	—	—	(244)	—	(244)
Net loss	—	—	—	—	(51,321)	(51,321)
Balances at December 31, 2024	29,919,634	$ —	$ 287,594	$ 31	$ (205,776)	$ 81,849

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

AN2 THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (51,321)	$ (64,732)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,338	8,412
Non-cash operating lease expense	—	53
Net accretion of discount on investments	(3,279)	(2,855)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	807	(1,026)
Accounts payable	641	553
Accrued compensation	(2,342)	1,850
Accrued liabilities	(2,227)	3,844
Operating lease liabilities	—	(53)
Other current liabilities	126	666
Net cash used in operating activities	(49,257)	(53,288)
Cash flows from investing activities		
Purchases of investments	(46,751)	(132,178)
Maturities of investments	101,340	88,900
Net cash provided by (used in) investing activities	54,589	(43,278)
Cash flows from financing activities		
Proceeds from issuance of common stock from the Underwritten Offering, net of commissions and offering expenses	—	65,479
Proceeds from issuance of common stock from the “at-the-market” offering, net of commissions and offering expenses	—	19,050
Proceeds from issuance of common stock under the ESPP	147	366
Proceeds from exercise of stock options	225	99
Net cash provided by financing activities	372	84,994
Net increase (decrease) in cash and cash equivalents	5,704	(11,572)
Cash and cash equivalents at the beginning of the period	15,647	27,219
Cash and cash equivalents at the end of the period	$ 21,351	$ 15,647

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

Note 1. Organization and Description of the Business

Description of Business

AN2 Therapeutics, Inc. (the "Company") is a biopharmaceutical company focused on discovering and developing novel small molecule therapeutics derived from its boron chemistry platform. The Company has a pipeline of boron-based compounds in development for Chagas disease, non-tuberculous mycobacterial ("NTM"), and melioidosis, along with early-stage programs focused on targets in infectious diseases and oncology. The Company was incorporated in the state of Delaware in February 2017, began operations in November 2019, began trading on the Nasdaq Global Select Market on March 25, 2022 under the symbol "ANTX", and is based in Menlo Park, California.

Since launching operations in November 2019, the Company has devoted substantially all of its resources to performing research and development activities, including with respect to its initial product candidate, epetraborole, and other product candidates, business planning and restructuring, hiring personnel, raising capital, and providing general and administrative support for these operations.

Initial Public Offering

On March 24, 2022, the Company's registration statement on Form S-1 (File No. 333-263295) relating to its initial public offering ("IPO") of common stock became effective. The IPO closed on March 29, 2022, at which time the Company issued an aggregate of 4,600,000 shares of its common stock at a price to the public of $15.00 per share. In addition, immediately prior to the closing of the IPO, all outstanding shares of the Company's then existing redeemable convertible preferred stock automatically converted into 11,409,488 shares of common stock. The aggregate offering proceeds for shares sold in the IPO was $69.0 million. After deducting underwriting discounts and commissions of $4.8 million and offering costs paid or payable by the Company of $3.3 million, the net proceeds from the offering were approximately $60.9 million.

On April 8, 2022, the underwriters from the IPO exercised an option to purchase 690,000 additional shares of the Company's common stock at a public offering price of $15.00 per share, resulting in additional gross proceeds to the Company of $10.4 million, and additional net proceeds of approximately $9.5 million. After giving effect to this exercise of the overallotment option, the total number of shares sold by the Company in the IPO increased to 5,290,000 shares with total net proceeds to the Company of approximately $70.4 million.

At-The-Market Offering

On April 6, 2023, the Company entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC as the Company's sales agent ("Agent") to issue and sell up to an aggregate gross sales of $100.0 million in shares ("Shares") of the Company's common stock through an "at-the-market" equity offering program ("ATM Offering"). The Company will pay commissions to the Agent of up to 3.0% of the gross proceeds of the sale of the Shares sold under the Sales Agreement and reimburse the Agent for certain expenses. During the year ended December 31, 2023, the Company issued and sold 2,502,000 shares of common stock under the ATM Offering, resulting in net proceeds of $19.1 million, after deducting commissions and other offering costs. The Company did not sell any shares of common stock through the ATM Offering during the year ended December 31, 2024.

Underwritten Offering

On August 15, 2023, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Cowen and Company, LLC, Leerink Partners LLC and Evercore Group L.L.C., as representatives of several underwriters, to issue and sell 7,777,778 shares of common stock at an offering price of $9.00 per share, resulting in net proceeds of $65.5 million, after deducting commissions and other offering costs (the "Underwritten Offering").

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). Certain reclassifications have been made to the prior year presentation to conform to the current year presentation. The prior year presentation of "other income, net" on the statements of operations and comprehensive loss has been separated to "interest income" and "other income" and conformed to reflect the current year's presentation.

Risks and Uncertainties

Liquidity

Prior to the IPO, the Company's operations had historically been financed through the issuance of redeemable convertible preferred stock. Since inception, the Company has incurred significant losses and negative net cash flows from operations. During the years ended December 31, 2024 and 2023, the Company incurred a net loss of $51.3 million and $64.7 million, respectively, and had cash flows used in operating activities of $49.3 million and $53.3 million, respectively. The Company has an accumulated deficit of $205.8 million and $154.5 million as of December 31, 2024 and 2023, respectively, and will require substantial additional capital for research and development activities. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development.

As of December 31, 2024, the Company had cash, cash equivalents, short-term investments and long-term investments of $88.6 million. Management believes that its cash, cash equivalents and investments as of December 31, 2024 will be sufficient to fund its current operating plan through at least 12 months from the issuance date of these financial statements. Future capital requirements will depend on many factors, including the timing and extent of spending on research and development, including costs for preclinical and nonclinical studies, clinical trials, and clinical trial and material manufacturing. There can be no assurance that, in the event the Company requires additional financing, such financing will be available at terms acceptable to the Company, if at all. Failure to generate sufficient cash flows from operations, raise additional capital, and reduce discretionary spending should additional capital not become available could have a material adverse effect on the Company's ability to achieve its intended business objectives.

Segments

The Company operates and manages its business as one reportable and operating segment. For financial information related to the Company's one operating segment see Note 13 - Segment Reporting.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to research and development accruals, fair value of assets and liabilities and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Research and Development Expenses

All research and development costs, including work performed by third parties, are expensed as incurred. Research and development costs consist of salaries and other personnel-related expenses, including associated stock-based compensation, consulting fees, and facility costs, as well as fees paid to other entities that conduct certain research and development activities on behalf of the Company. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods are received or services are rendered.

As part of the process of preparing its financial statements, the Company estimates its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on the Company's behalf and estimating the level of services performed and the associated cost incurred for services for which the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its accrued expenses at the end of each reporting period based on the facts and circumstances known to the Company at that time. The significant estimates in the Company's accrued research and development expenses relate to expenses incurred with respect to contract manufacturing and clinical and other research organizations, academic research centers and other vendors in connection with research and development activities for which the Company has not yet been invoiced.

Stock-Based Compensation

The Company measures and recognizes compensation expense for equity-classified stock-based awards made to employees, directors and non-employees based on the grant date estimated fair value of each award. Compensation expense for employee and director awards is recognized on a straight-line basis over the requisite service period which is generally the vesting period for the entire award. Expense is adjusted for forfeitures as they occur. Compensation expense for non-employee awards is recognized in the same period and manner as if the Company had paid cash for the goods or services provided.

The valuation model used for calculating the fair value of stock options for stock-based compensation expense is the Black-Scholes option-pricing model (the Black-Scholes model). The Black-Scholes model requires management to make assumptions and judgments about the variables used in the calculation, including the expected term, the expected volatility of common stock, an assumed risk-free interest rate, and expected dividends the Company may pay. Management uses the simplified calculation (based on the mid-point between the vesting date and the end of the contractual term) of the expected term for its stock options as the Company has concluded that its stock option history does not provide a reasonable basis upon which to estimate expected term. Volatility is based on an average of the historical volatilities of the common stock of entities with characteristics similar to the Company's. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The Company uses an assumed dividend yield of zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

For option awards that contain performance conditions, compensation cost is recognized in the period in which it becomes probable that the performance condition will be satisfied. For option awards that vest upon a liquidity event or a change in control, the performance condition is not probable of being achieved until the event occurs. As a result, no compensation expense would be recognized until the performance-based vesting condition is achieved.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents, which consist of money market funds, corporate debt securities and corporate commercial paper, are stated at fair value. As of December 31, 2024 and 2023, the Company had cash and cash equivalents of $21.4 million and $15.6 million, respectively.

Investments

Investments consist of U.S. Treasury securities, commercial paper, U.S. Government agency securities, asset-backed securities, and corporate debt securities. All of the Company's investments are classified as available-for-sale and are carried at estimated fair values and reported in cash equivalents, short-term investments or long-term investments. Management determines the appropriate classification of the investments at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. Investments with contractual maturities greater than 12 months are considered long-term investments. The cost of investments sold, if any, is based on the specific identification method.

Unrealized gains and losses on available-for-sale investments are reported in accumulated other comprehensive gain (loss) as a separate component of stockholders' equity. For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value and recognized in other income (expense) in the statements of operations and comprehensive loss. If neither criterion is met, the Company evaluates whether the decline in fair value is related to credit-related factors or other factors. In making this assessment, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. Credit-related impairment losses, limited by the amount that the fair value is less than the amortized cost basis, are recorded through an allowance for credit losses in other income, net. Any unrealized losses from declines in fair value below the amortized cost basis as a result of non-credit factors are recognized in accumulated other comprehensive income (loss) as a separate component of stockholders' equity, along with unrealized gains. Realized gains and losses and declines in fair value, if any, on available-for-sale securities are included in other income, net in the statements of operations and comprehensive loss.

For purposes of identifying and measuring credit-related impairments, the Company's policy is to exclude applicable accrued interest from both the fair value and amortized cost basis of the related security. The Company has elected to write-off uncollectible accrued interest receivable balances in a timely manner, which is defined by the Company as when interest due becomes 90 days delinquent. The accrued interest write-off will be recorded by reversing interest income. Accrued interest receivable is recorded to prepaid expenses and other current assets. There have been no uncollectible accrued interest write-offs in the years ended December 31, 2024 or 2023.

As of December 31, 2024 and 2023, the Company had investments of $67.3 million and $118.8 million, respectively.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents and investments. The Company's cash is invested through financial institutions in the United States. The Company's investments consist of debt securities, issued by highly rated corporate entities or the U.S. government, and asset-backed securities. The Company's exposure to any individual corporate entity is limited by its investment policy. Deposits have and will continue to exceed federally insured limits. The Company invests its cash equivalents in highly rated money market funds. The Company has not experienced any credit losses in such accounts.

The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash to the extent recorded on the balance sheets. In March 2023, one of the financial institutions utilized by the Company was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Through December 31, 2024, the Company has no off-balance sheet concentrations of credit risk.

Government Contract

In September 2022, the Company received a cost-reimbursement contract award under which the Company is eligible to receive up to $17.8 million from the U.S. National Institute of Allergy and Infectious Diseases ("NIAID") to support preclinical, Phase 1 studies and other activities to enable advancement of epetraborole into late-stage development for acute systemic melioidosis and other biothreat pathogens. This project will be funded in whole or in part with Federal funds from the NIAID, National Institutes of Health, Department of Health and Human Services, and Department of Defense Contract No. 75N93022C00059. Accounting for this contract does not fall under ASC 606, Revenue from Contracts with Customers, as NIAID will not benefit directly from the advancement of epetraborole. As there is no authoritative guidance under U.S. GAAP on accounting for government assistance to for-profit business entities, the Company applied International Accounting Standards (IAS) 20, Accounting for Government Grants and Disclosure of Government Assistance, by analogy when accounting for the NIAID contract payments to the Company. Under IAS 20, government contract proceeds are recognized when there is reasonable assurance the conditions of the contract will be met and the contract funding will be received. For the NIAID contract, this occurs after the qualifying expenses related to the contract have been incurred, or the Company concludes the conditions of the contract have been substantially met. The income related to the reimbursement of operating expenses is then recorded as a reduction of those expenses (see Note 4 - Funding Arrangements).

Grant Agreements

In September 2022, the Company entered into a subcontract agreement with the University of Georgia Research Foundation ("UGARF") to receive up to $1.4 million from the UGARF to support preclinical development of a boron-containing small molecule for Chagas disease.

In September 2023, the Company entered into a grant agreement with the Bill and Melinda Gates Foundation ("BMGF") to fund up to $1.8 million to generate new boron-based lead compounds with the potential to be developed into drugs that treat tuberculosis ("TB") and malaria.

In July 2024, the Company entered into an amendment to the 2022 subcontract agreement with the UGARF for additional funding in the amount of $0.2 million.

In September 2024, the Company entered into a second-year continuation grant agreement with BMGF to fund up to $2.0 million to support an early-stage research program focused on delivering novel leads as starting points for new drugs that can be combined to deliver shorter, safer and simpler TB drug regimens.

The Company recognizes grant proceeds in accordance with ASC 958-605, Not-for-Profit Entities - Revenue Recognition, when qualifying costs are incurred and the conditions of the grant agreement have been met. When receipt of grant proceeds is reasonably assured, the Company records a reduction to the research and development expenses incurred and a corresponding grant receivable. Cash received from grants in advance of incurring qualifying costs is recorded as a liability and recognized as a reduction to the qualifying research and development expenses incurred (see Note 4 - Funding Arrangements).

Comprehensive Loss

Comprehensive loss includes net loss and certain changes in stockholders' equity that are excluded from net loss. The Company's other comprehensive loss consists of net changes in unrealized gains and losses on its available-for-sale investments. For the years ended December 31, 2024 and 2023, the Company had $0.2 million of net unrealized loss and $0.6 million of net unrealized gain on available-for-sale investments, respectively.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, stock options, unvested RSUs, common stock subject to repurchase related to unvested early exercise of stock options, and shares committed under ESPP are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of early exercised shares subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods because the impact of potentially dilutive securities would be anti-dilutive.

Restructuring Charges

Restructuring charges consist primarily of employee severance payments and other employee termination-related expenses. The Company records restructuring charges based on whether the termination benefits are provided under an on-going benefit arrangement or under a one-time benefit arrangement. The Company accounts for on-going benefit arrangements, such as those documented by employment agreements or a pre-existing severance policy, in accordance with ASC 712, Nonretirement Postemployment Benefits. Under ASC 712, liabilities for postemployment benefits are recorded at the time the obligations are probable of being incurred and can be reasonably estimated. The Company accounts for one-time employment benefit arrangements in accordance with ASC 420, Exit or Disposal Cost Obligations.

JOBS Act Accounting Election

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date the Company (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. The Company may take advantage of these provisions for up to five years (which is through March 2027), unless the Company ceases to be an emerging growth company at an earlier date. As a result, these financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"). The amendments in ASU 2023-07 are intended to improve reportable segment disclosure, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for annual periods beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements. Early adoption is permitted. The Company adopted ASU 2023-07 on January 1, 2024, retrospectively. Newly required disclosures have been included in Note 13 - Segment Reporting.

Recent Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise noted, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial statements and disclosures. As an "emerging growth" company, it has been the Company's intention to take advantage of certain temporary exemptions from various reporting requirements, as well as taking advantage of additional transitional relief.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). ASU 2023-09 requires enhanced annual disclosures regarding the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 and may be adopted on a prospective or retrospective basis. Early adoption is permitted. The Company is evaluating the impact of this guidance on its financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03") and in January 2025, the FASB issued ASU No. 2025-01, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date*, which clarified the effective date of ASU 2024-03. ASU 2024-03 will require the Company to disclose the amounts of purchases of inventory, employee compensation, depreciation and intangible asset amortization, as applicable, included in certain expense captions in the Statements of Operations, as well as qualitatively describe remaining amounts included in those captions. ASU 2024-03 will also require the Company to disclose both the amount and the Company's definition of selling expenses. ASU 2024-03 is effective for annual periods beginning after December 15, 2026 and may be adopted on a prospective or retrospective basis. Early adoption is permitted. The Company is evaluating the impact of this standard on its financial statements and related disclosures.

Note 3. Fair Value Measurements

The Company adopted ASU 2016-13 beginning January 1, 2023. The Company records certain financial assets and liabilities at fair value. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

- Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.
- Level 2: Inputs other than Level I that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's primary financial instruments include cash, cash equivalents and investments, prepaid expenses, accounts payable, and accrued liabilities. The carrying amounts of the Company's financial instruments, other than cash equivalents and investments, approximate fair value due to their relatively short maturities.

The following table presents the Company's financial assets, which consist of cash equivalents and investments classified as available-for-sale investments, that are measured at fair value on a recurring basis (in thousands):

		December 31, 2024			
	Level	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Cash equivalents:					
Money market funds	Level 1	$ 10,127	$ —	$ —	$ 10,127
Short-term investments:					
U.S. Treasury securities	Level 1	25,906	24	—	25,930
Commercial paper	Level 2	30,842	11	(14)	30,839
U.S. Government agency securities	Level 2	3,499	6	—	3,505
Corporate debt securities	Level 2	1,991	2	—	1,993
Long-term investments:					
U.S. Treasury securities	Level 1	5,019	2	—	5,021
Total		$ 77,384	$ 45	$ (14)	$ 77,415

		December 31, 2023			
	Level	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Cash equivalents:					
Money market funds	Level 1	$ 4,478	$ —	$ —	$ 4,478
Short-term investments:					
U.S. Treasury securities	Level 1	15,649	31	—	15,680
U.S. Treasury securities	Level 2	1,247	—	(1)	1,246
Commercial paper	Level 2	41,472	47	(2)	41,517
U.S. Government agency securities	Level 2	19,479	30	(5)	19,504
Asset-backed securities	Level 2	8,770	12	(3)	8,779
Corporate debt securities	Level 2	4,914	8	—	4,922
Long-term investments:					
U.S. Treasury securities	Level 1	23,542	131	—	23,673
U.S. Government agency securities	Level 2	3,494	28	(1)	3,521
Total		$ 123,045	$ 287	$ (12)	$ 123,320

The Company classifies its money market funds and U.S. Treasury securities, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

The Company classifies its investments in commercial paper, corporate debt securities, U.S. government agency securities, U.S. Treasury securities and asset-backed securities as Level 2 within the fair value hierarchy. The fair values of these investments are estimated by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs. There were no transfers of financial instruments between valuation levels during the year ended December 31, 2024.

As of December 31, 2024, none of the Company's available-for-sale investments that were in an unrealized loss position had been in an unrealized loss position for more than 12 months. During the years ended December 31, 2024 and 2023, the Company did not sell any available-for-sale investments.

The Company's short-term investments had maturities of less than one year from the balance sheet date. The Company's long-term investments had maturities of between one and two years from the balance sheet date.

The Company does not intend to sell the securities in an unrealized loss position and does not expect they will be required to sell the securities before recovery of the unamortized cost basis. Additionally, the Company evaluated its securities for credit losses and considered the decline in market value to be primarily attributable to current economic and market conditions and not credit related. Accordingly, no allowance for credit losses has been recognized as of December 31, 2024 and 2023. During the years ended December 31, 2024 and 2023, the Company did not recognize any impairment losses related to investments.

As of December 31, 2024 and 2023, the Company had accrued interest receivable of $0.3 million and $0.4 million, respectively, which was included in prepaid expenses and other current assets on the balance sheets.

Note 4. Funding Arrangements

NIAID Contract

In September 2022, the Company received a cost-reimbursement contract award from the NIAID to support preclinical, Phase 1 studies and other activities to enable the advancement of epetraborole into late-stage development for acute systemic melioidosis and other biothreat pathogens. The Company is eligible to receive up to $17.8 million in funding over a total term of 48 months, consisting of a base period and seven option periods. In July 2023 and May 2024, the NIAID exercised two of seven available options under the NIAID contract (No: 75N93022C00059), resulting in an increase in committed contract funding of $0.7 million and $3.8 million, respectively, for a cumulative total of $8.8 million. Funding for these options extends the estimated completion of the current contract by 29 months beyond the base period of 18 months to August 2026. As of December 31, 2024, a total of $8.8 million of funding for the 18-month base period plus an additional 29 months for a total of 47 months has been committed.

As of December 31, 2024 and 2023, the Company had recorded a receivable of zero and $0.4 million, respectively, which was included in prepaid expenses and other current assets on the balance sheets. During the years ended December 31, 2024 and 2023, the Company recorded $1.8 million and $0.9 million of income under the NIAID contract as a reduction in research and development operating expenses.

UGARF Grant

In September 2022, the Company entered into a subcontract agreement with the UGARF to conduct preclinical activities on behalf of UGARF (“UGARF Agreement”). The UGARF reimburses the Company under an award from Wellcome. The Company received $1.4 million from the UGARF to support preclinical development of a boron-containing small molecule for Chagas disease. In July 2024, the Company signed an amendment to the UGARF Agreement for additional funding in the amount of $0.2 million. As of December 31, 2024 and 2023, the Company had recorded a grant receivable of zero and $0.6 million, respectively, which was included in prepaid expenses and other current assets on the balance sheets. During the years ended December 31, 2024 and 2023, the Company recorded income of $0.2 million and $1.3 million, respectively, as a reduction in research and development operating expenses under the UGARF agreement.

BMGF Grant

In September 2023, the Company received a cost-reimbursement contract award from the Bill and Melinda Gates Foundation (“2023 BMGF Agreement”) under which the Company was awarded $1.8 million to support the discovery of novel, boron containing small molecules for the treatment of tuberculosis and malaria. The Company is required to apply the funds it receives under the 2023 BMGF Agreement solely toward direct costs related to this research program. The Company received $1.0 million of funding in advance and tracks and reports eligible expenses incurred to the BMGF. In April 2024, the Company received $0.8 million in funding, making the grant fully funded.

In September 2024, the Company entered into a second-year continuation cost-reimbursement contract award with the Bill and Melinda Gates Foundation (“2024 BMGF Agreement”) under which the Company was awarded $2.0 million to support an early-stage research program focused on delivering novel leads as starting points for new drugs that can be combined to deliver shorter, safer and simpler TB drug regimens. The Company is required to apply the funds it receives under the 2024 BMGF Agreement solely toward direct costs related to this research program. The Company received $1.1 million of funding in advance and tracks and reports eligible expenses incurred to the BMGF. Any unspent funds and any funds spent that have not yet been incurred are recorded as part of other current liabilities on the balance sheets.

As of December 31, 2024 and 2023, the Company recorded $0.8 million and $0.7 million, respectively, to other current liabilities on the balance sheets. During the years ended December 31, 2024 and 2023, the Company recorded income of $1.7 million and $0.3 million, respectively, as a reduction in research and development operating expenses under the 2024 and 2023 BMGF Agreements.

Note 5. Collaboration and License Agreements

Anacor Licensing Agreement

In November 2019, the Company entered into an exclusive worldwide license agreement with Anacor Pharmaceuticals, Inc. ("Anacor") for certain compounds and other intellectual property controlled by Anacor for the treatment, diagnosis, or prevention of all human diseases (the "Anacor License"). The Anacor License will expire upon expiration of the last to expire royalty term. Either party may terminate the Anacor License for the other party's material breach following a cure period or immediately upon certain insolvency events relating to the other party. The Company has the right to terminate the agreement at its convenience upon 90-day written notice until the first regulatory approval or one-year notice thereafter. Furthermore, upon termination of the Anacor License for any of the foregoing reasons, the rights and licenses within will terminate.

In exchange for the worldwide, sublicensable, exclusive right and licenses to develop, manufacture, and commercialize the specified compounds, the Company paid Anacor a non-refundable $2.0 million upfront payment and granted Anacor shares of Series A redeemable convertible preferred stock.

The Company agreed to make further payments to Anacor upon achievement of various development milestones for an aggregate maximum of $2.0 million, upon achievement of various commercial and sales threshold milestones for an aggregate maximum payment of $125.0 million, and up to 50% of royalties received under certain sublicensing arrangements. Royalties are subject to certain customary reductions, including lack of patent coverage and generic product entry. The Company also agreed to pay Anacor non-refundable, non-creditable sales royalties on a tiered marginal royalty rate based on the country's status as a developing or developed country as defined in the license agreement. Sales royalties are a percentage of net sales, as specified in the Anacor License, and range from mid-single digits for developing countries (as classified by the World Bank) and single to mid-teens for all other countries or the China, Hong Kong, Taiwan, and Macau territories, upon reaching a minimum of net sales in the low-teen millions. The sales royalties are required to be paid on a product-by-product and country-by-country basis, until the latest to occur of 15 years following the date of first commercial sale of a product, the expiration of all regulatory or data exclusivity, or the date upon of the expiration of the last to expire valid claim of a licensed patent covering such product in such country. Currently, the date of the expiration of the last to expire valid claim of a licensed patent covering epetraborole in the licensed territory is June 2028. In addition, Anacor is entitled to certain milestone payments upon a change of control of the Company.

In December 2021, the Company entered into an amendment to the Anacor License for certain compounds and other intellectual property controlled by Anacor for the treatment, diagnosis, or prevention of certain bacterial pathogens (the "Anacor License Amendment"). The Anacor License Amendment has no impact on the Anacor License financial terms.

None of the development, regulatory, commercial or sales milestones or royalty payments were recognized during the years ended December 31, 2024 and 2023.

Brii Biosciences Agreement

In November 2019, the Company entered into a license agreement granting Brii Biosciences Limited the exclusive development and commercialization rights of certain compounds in China, Hong Kong, Taiwan, and Macau for the treatment of human diseases. The Company did not receive an upfront payment but is eligible to receive up to $15.0 million in the aggregate for development and regulatory milestones and up to $150.0 million in commercial milestones upon achieving sales thresholds. The Company is also entitled to tiered mid-single digits to high-first decile percentage sales-based royalties. The sales royalties are required to be paid on a product-by-product and region-by-region basis, until the latest to occur of 15 years following the date of first commercial sale of a product, the expiration of all regulatory or data exclusivity, or the date upon the expiration of the last to expire claim of a licensed patent covering the composition of matter or approved use of such product in such region. The last to expire valid claim of a licensed patent covering the composition of matter or approved use of such product in the licensed territory is June 2028. Future milestone payments and royalties will be accounted for under ASC 606.

Note 6. Balance Sheet Components

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Accrued clinical trial-related expenses	$ 2,377	$ 4,809
Accrued research and development-related expenses	1,974	1,746
Accrued professional services expenses	52	24
Other	51	102
Total accrued liabilities	$ 4,454	$ 6,681

Note 7. Commitments and Contingencies

Contingencies

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company was not subject to any material legal proceedings as of December 31, 2024 and 2023, and the Company is not currently a party to any legal proceeding that, if determined adversely to the Company, in management's opinion, is currently expected to individually or in the aggregate have a material adverse effect on the Company's business, financial condition or results of operations taken as a whole.

Guarantees and Indemnifications

The Company, as permitted under Delaware law and in accordance with its certification of incorporation, as amended, and bylaws, and pursuant to indemnification agreements with certain of its officers and directors, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, which the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance limits the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

Adjuvant Global Health Agreement

In conjunction with Adjuvant Global Health Technology Fund L.P.'s ("Adjuvant") investment in the Company in 2019 and 2020, the Company entered into a Global Health Agreement with Adjuvant, pursuant to which the Company agreed to support the creation of innovative and affordable drugs to treat disease, through public health programs and private purchasers in Low and Lower-Middle-Income Countries (as such terms are defined by the World Bank and in the agreement).

Adjuvant's investment supports the development of the Company's product candidate, epetraborole, for use in melioidosis-endemic and melioidosis-at-risk countries and in tuberculosis-endemic and tuberculosis-at-risk countries, as defined in the agreement as amended and restated. These global access commitments will remain in effect until the latter of either that Adjuvant ceases to be a shareholder of the Company, or ten years following epetraborole approval for the treatment of melioidosis by a regulatory authority.

The Global Health Agreement contains various affirmative and negative covenants agreed to by the Company, including its use of reasonably diligent endeavors to develop the agreed-upon products using non-dilutive funding and make accessible to people in need in the target countries so long as the Company does not sell products at a loss. Other covenants include prohibition of use of investment for propaganda, attempt to influence legislation, influence of any public election or voter registration drive or promotion of terrorist activities, as well as compliance with certain environmental, social and governance requirements and anti-corruption requirements.

Note 8. Equity

Common Stock

The Company's certificate of incorporation, as amended, authorizes the Company to issue up to 500,000,000 shares of $0.00001 par value common stock. Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

Subject to the preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board. No dividends have been declared to date.

In April 2023, the Company entered into a Sales Agreement with Cowen and Company, LLC as the Company's Agent, to issue and sell up to an aggregate gross sales of $100.0 million in Shares of the Company's common stock through the ATM Offering. During the year ended December 31, 2023, the Company issued and sold 2,502,000 shares of common stock under the ATM Offering, resulting in net proceeds of $19.1 million, after deducting commissions and other offering costs. The Company did not sell any shares of common stock through the ATM Offering during the year ended December 31, 2024.

In August 2023, the Company entered into an Underwriting Agreement with Cowen and Company, LLC, Leerink Partners LLC and Evercore Group L.L.C. as representatives of several underwriters to issue and sell 7,777,778 shares of common stock at an offering price of $9.00 per share through the Underwritten Offering, resulting in net proceeds of $65.5 million, after deducting commissions and other offering costs.

Shares of common stock reserved for future issuance, on an as-if-converted basis, as of December 31, 2024 and 2023, consists of the following:

	December 31, 2024	December 31, 2023
Stock options, issued and outstanding	4,890,843	3,930,306
Unvested restricted stock units	516,511	—
Stock options, authorized for future issuance	859,841	1,254,721
ESPP, authorized for future issuance	563,731	337,017
Total	6,830,926	5,522,044

Preferred Stock

The Company's certificate of incorporation, as amended, authorizes the Company to issue up to 10,000,000 shares of $0.00001 par value preferred stock. The preferred stock is not convertible. No shares of preferred stock were issued and outstanding at December 31, 2024 and 2023.

Shareholder Rights Plan

In August 2024, the Company entered into a Rights Agreement between the Company and Equiniti Trust Company, LLC as Rights Agent (as amended from time to time, the "Rights Agreement"), which was previously approved by the Board. In connection with the Rights Agreement, a dividend was declared of one preferred stock purchase right (individually, a "Right" and collectively, the "Rights") for each share of the common stock, par value $0.00001 per share, of the Company outstanding at the close of business on August 29, 2024 (the "Record Date"). Each Right entitles the registered holder thereof, after the Rights become exercisable and until August 15, 2025 (or the earlier redemption, exchange or termination of the Rights), to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value $0.00001 per share (the "Series A Preferred"), of the Company at a price of $6.50 per one one-thousandth of a share of Series A Preferred, subject to adjustment. The Rights are not exercisable until the Distribution Date (as defined in the Rights Agreement") and the Rights will expire on August 15, 2025, subject to the Company's right to extend such date, unless earlier redeemed or exchanged by the Company or terminated. Additional information regarding the Rights Agreement is contained in a Current Report on Form 8-K filed with the SEC. The adoption of the Shareholder Rights Plan had no impact on the financial position of the Company.

Note 9. Equity Incentive Plan and Stock-Based Compensation

2022 Equity Incentive Plan

The Company adopted the 2022 Equity Incentive Plan (the "2022 Plan") effective upon the closing of the IPO, which provides for the granting of incentive stock options ("ISOs") to the Company's employees, and for the grant of nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, and other forms of awards to employees, directors, and consultants. As of December 31, 2024, no stock appreciation rights or performance awards were issued.

The Company initially reserved for issuance 1,870,000 new shares of common stock pursuant to the 2022 Plan. The Company's 2017 Equity Incentive Plan (the "2017 Plan") was terminated in 2022; however, shares underlying outstanding stock awards granted under the 2017 Plan will continue to be governed by the 2017 Plan. Shares available under the 2017 Plan were added to the available shares in the 2022 Plan. Shares underlying outstanding stock awards granted under the 2017 Plan that expire or are repurchased by, forfeited to, cancelled or withheld by the Company will also be reserved for issuance under the 2022 Plan.

The initial number of shares of the Company's common stock that may be issued under the 2022 Plan will not exceed 4,423,920 shares of the Company's common stock, which is the sum of (i) 1,870,000 new shares, plus (ii) 2,553,920 shares related to the 2017 Plan. In addition, the number of shares of the Company's common stock reserved for issuance under the 2022 Plan will automatically increase on January 1 of each year for a period of ten years, beginning on January 1, 2023 and continuing through January 1, 2032, in an amount equal to (1) 4% of the total number of shares of the Company's common stock outstanding on December 31 of the immediately preceding year, or (2) a lesser number of shares determined by the Company's board of directors no later than December 31 of the immediately preceding year. Accordingly, effective January 1, 2024, the number of shares in the 2022 Plan increased by 1,189,657 shares, representing 4% of the prior year end's common stock outstanding. The maximum number of shares of the Company's common stock that may be issued on the exercise of stock options or vesting of RSUs and RSAs under the 2022 Plan is 13,271,760 shares.

Since the date of incorporation and through December 31, 2024, the Company issued stock options, RSUs and RSAs to its employees, directors and consultants. As of December 31, 2024, 859,841 shares of common stock remained available for future issuance under the 2022 Plan.

ISOs granted to newly hired employees under the 2022 Plan generally vest 25% after the completion of 12 months of service, and the balance vests in equal monthly installments over the next 36 months of service and expire ten years from the grant date, unless subject to provisions regarding 10% stockholders. ISOs granted to existing employees generally vest ratably over a 48-month period of service and expire ten years from the grant date. NSOs vest in accordance with the terms of the specific agreement under which the options were provided and expire ten years from the date of grant. RSUs granted to employees generally vest annually over a two to four year period of service and expire ten years from the grant date. RSAs granted to non-employees generally vest at the time of grant and expire ten years from the grant date.

Stock-Based Compensation Expense

The following table summarizes the components of stock-based compensation expense recognized in the Company's statements of operations and comprehensive loss during the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development expenses	$ 3,798	$ 4,236
General and administrative expenses	4,540	4,176
Total	$ 8,338	$ 8,412

Valuation of Stock Options

The Company estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of employee and non-employee stock options is being amortized on the straight-line basis over the requisite service period of the awards.

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—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual term of the stock-based awards.
- Expected Volatility—Since the Company has limited trading history for its common stock, the expected volatility is based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle and area of specialty.
- Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of option.
- Expected Dividend Rate—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The following weighted average assumptions were used to value options granted during the periods indicated:

	Year Ended December 31, 2024	Year Ended December 31, 2023
Expected term	5.94 years	5.98 years
Expected volatility	110.6 %	90.8 %
Risk-free interest rate	4.28 %	4.04 %
Expected dividend yield	—	—

Stock Option Activity

A summary of the stock plan activity is as follows:

	Total Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	3,930,306	$ 10.86	8.14	$ 37,853
Granted	1,700,899	2.42		
Exercised	(28,930)	7.78		
Forfeited/expired	(711,432)	8.91		
Vested and expected to vest at December 31, 2024	4,890,843	$ 8.23	6.66	$ 330
Exercisable as of December 31, 2024	2,883,622	$ 9.45	5.46	$ 263

As of December 31, 2024, there was unrecognized stock-based compensation expense of $8.3 million related to unvested stock options which the Company expects to recognize over a weighted-average period of 1.6 years.

Weighted-average grant-date fair value of the options granted during the year ended December 31, 2024 was $2.05 per share.

RSU Activity

RSUs entitle the holder to receive shares of the Company's common stock upon vesting. The fair value of RSUs is based upon the closing sales price of the Company's common stock on the grant date.

A summary of the RSU activity is as follows:

	Number of Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2023	—	$ —
Issued	762,346	2.59
Vested and released	(38,556)	2.96
Forfeited	(207,279)	2.63
Unvested at December 31, 2024	516,511	$ 2.54

As of December 31, 2024, there was unrecognized stock-based compensation expense of $0.9 million related to unvested restricted stock units which the Company expects to recognize over a weighted-average period of 2.3 years.

RSA Activity

RSAs entitle the holder to receive shares of the Company's common stock upon vesting. The fair value of RSAs is based upon the closing sales price of the Company's common stock on the grant date.

A summary of the RSA activity is as follows:

	Number of Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2023	—	$ —
Issued	40,003	1.27
Vested and released	(40,003)	1.27
Forfeited	—	—
Unvested at December 31, 2024	—	$ —

As of December 31, 2024, there was no unrecognized stock-based compensation expense related to unvested restricted stock awards.

Liability for Early Exercise of Stock Options

The Company's 2017 Plan permitted early exercise of certain stock options prior to vesting to certain directors, officers, and employees. Any shares issued pursuant to unvested options are restricted and subject to repurchase by the Company until the conditions for vesting are met. The amounts paid for shares purchased under an early exercise of stock options and subject to repurchase by the Company are reported as options subject to repurchase, short and long-term on the balance sheet and is reclassified to common stock and additional paid-in capital as such shares vest. Upon termination of employment of an option-holder, the Company has the right to repurchase, at the original purchase price, any unvested options.

As of December 31, 2024, and 2023, there were none and 5,040 unvested common shares outstanding that were issued upon the early exercise of stock options prior to the vesting of the underlying shares which are subject to repurchase by the Company at the original issuance price upon termination of the stockholders' services. The right to repurchase these shares generally lapses with respect to 25% of the shares underlying the option after one year of service to the Company and 1/48th of the shares underlying the original grant per month for 36 months thereafter. The shares purchased by the option-holders pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be issued until those shares vest. As of December 31, 2023, the Company recorded an insignificant amount of liabilities associated with the cash received for shares issued subject to repurchase rights, recorded within the options subject to repurchase, short-term, and options subject to repurchase, long-term on the Company's balance sheets.

2022 Employee Stock Purchase Plan

The Company's 2022 Employee Stock Purchase Plan ("ESPP") has two components: a component that is intended to qualify as an "employee stock purchase plan" under Section 423 of the Code (the "423 Component") and a component that is not intended to qualify (the "Non-423 Component"). The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation. At the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock at the beginning of the offering period or at the end of each applicable purchase period.

Subject to adjustment in the case of certain capitalization events, 187,000 shares of the Company's common stock were available for purchase at the adoption of the ESPP. Pursuant to the ESPP, the annual share increase pursuant to the evergreen provision is determined based on the least of (i) 1% of the Company's common stock outstanding as of December 31 of the immediately preceding year, (ii) 561,000 shares, or (iii) such number of shares as determined by the Board. Accordingly, effective January 1, 2024, the number of shares in the ESPP increased by 297,414 shares, representing 1% of the prior year-end's common stock outstanding. As of December 31, 2024, 563,731 shares of common stock remained available for issuance under the ESPP.

During the years ended December 31, 2024 and 2023, the Company recognized $0.1 million and $0.2 million, respectively, in stock-based compensation expense related to the ESPP.

Note 10. Income Taxes

The Company is liable for income taxes in the United States. For the years ended December 31, 2024 and 2023, the Company did not have any income for income tax purposes and therefore, no tax liability or expense has been recorded in these financial statements.

The provision for income taxes differs from the tax expense that would result by applying the statutory federal income tax rate to loss before taxes due to the following (in thousands):

	December 31,	
	2024	2023
Federal tax benefit at statutory rate	$ (10,777)	$ (13,593)
State tax benefit at statutory rate, net of federal tax benefit	(3,892)	(4,917)
Change in valuation allowance	16,289	20,047
Research and development tax credits	(1,980)	(2,030)
Other	360	493
Provision for income taxes	$ —	$ —

The following table reflects the effective income tax rate reconciliation for the years ended December 31, 2024 and 2023:

	December 31,	
	2024	2023
Statutory rate	21.0%	21.0%
Stock-based compensation	(0.7%)	(0.7%)
State taxes, net of the federal tax benefit	7.6%	7.6%
R&D credit benefit	3.9%	3.1%
Change in valuation allowance	(31.8%)	(31.0%)
Total	0.0%	0.0%

Recognition of deferred tax assets is appropriate when realization of such assets is more likely than not. Based upon the weight of available positive and negative evidence, which includes the Company's historical operating performance and the U.S. cumulative net losses in all prior periods, the Company has provided a valuation allowance against its U.S. deferred tax assets. The valuation allowance increased by $16.3 million from December 31, 2023 to December 31, 2024 due to generation of current year net operating losses, capitalization of research and development costs, and research and development credits claimed.

Deferred income taxes reflect the net tax effects of losses, credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets		
Net operating loss carryforwards	$ 28,682	$ 20,778
Capital research expenditures	18,308	14,014
Tax credit carryforwards	6,788	4,406
Stock-based compensation	4,324	2,568
Other	5	52
Gross deferred tax assets	58,107	41,818
Valuation allowance	(58,107)	(41,818)
Net deferred tax assets	$ —	$ —

As of December 31, 2024, the Company had $81.3 million of federal and $166.3 million of state net operating loss available to offset future taxable income. The federal net operating loss carryforwards do not expire. The state net operating loss carryforwards begin to expire in 2037. The Company also has federal and California state research and development credits of $5.4 million and $1.8 million, respectively. The federal tax credit carryforwards will expire in 2041 if not utilized. The state tax credit carryforwards do not expire.

Utilization of the net operating loss carryforwards is subject to an annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions.

A Section 382 ownership change generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. The Company is not currently in a taxable position and no net operating loss carryforwards or credits have been used to date.

As of December 31, 2024 and 2023, the Company has unrecognized tax benefits of $2.1 million and $1.5 million, respectively. As of December 31, 2024, the total amount of unrecognized tax benefits would not affect the effective tax rate, if recognized, due to the valuation allowance that currently offsets deferred tax assets. The Company does not expect the unrecognized tax benefits to change significantly over the next 12 months. A reconciliation of the beginning and ending amount of unrecognized tax benefits for the years ended December 31, 2024 and 2023 was as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Balance at beginning of year	$ 1,461	$ 783
Additions related to current year positions	622	678
Balance at end of year	$ 2,083	$ 1,461

The Company recognizes interest and penalties related to unrecognized tax benefits within the income tax expense line in the statements of operations. Accrued interest and penalties are included within the related tax liability line in the balance sheet. No accrued interest and penalties have been recorded through December 31, 2024.

The Company files income tax returns in the U.S. federal jurisdiction and California, Illinois, New York, South Carolina and Virginia state jurisdictions. The Company is not currently under audit by the Internal Revenue Service or other similar state or local authorities. Carryover attributes beginning December 31, 2020 and December 31, 2019, respectively, remain open to adjustment by the U.S. and state taxing authorities to which the Company is subject.

Note 11. Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except for per share amounts):

	Year Ended December 31,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders	$ (51,321)	$ (64,732)
Denominator:		
Weighted-average common shares outstanding used to calculate net loss per share attributable to common stockholders, basic and diluted	29,828,227	23,600,107
Net loss per share attributable to common stockholders, basic and diluted	$ (1.72)	$ (2.74)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	December 31,	
	2024	2023
Options issued and outstanding	4,890,843	3,930,306
Unvested RSUs	516,511	—
Early exercised common stock subject to future vesting	—	5,040
ESPP authorized for future issuance	563,731	337,017
Total	5,971,085	4,272,363

Note 12. Restructuring Charges

On August 8, 2024, the Company announced a reduction of approximately 50% of the Company's workforce, which was approved by the Board in connection with the Company's planned restructuring following discontinuation of the EBO-301 study and to further extend the Company's operating capital. In connection with the workforce reduction, the Company recognized severance and other charges of $2.2 million for the year ended December 31, 2024, primarily related to severance payments and other employee termination-related expenses. The severance and other charges were recorded to restructuring charges on the statements of operations and comprehensive loss. The workforce reduction was complete by the end of 2024. Cash payments for severance and other charges of $2.2 million were made in the year ended December 31, 2024.

Note 13. Segment Reporting

The Company operates and manages its business as one reportable and operating segment. The determination of a single operating segment is consistent with the financial information regularly provided to the Company's chief operating decision maker (the "CODM"). The CODM assesses performance for the single segment and decides how to allocate resources based on net loss that also is reported on the statements of operations and comprehensive loss. The monitoring of budgeted versus actual results are used in assessing performance of the segment, and making operating decisions, allocating resources, and planning and forecasting for future periods. The measure of segment assets is reported on the balance sheets as total assets.

In addition to the significant expense categories included within net loss presented on the statements of operations and comprehensive loss, see below for disaggregated amounts that comprise research and development expenses:

	Year Ended December 31,	
	2024	2023
External research and development expenses:		
Clinical trials expenses	$ 15,626	$ 21,200
Consulting and outside services	4,707	4,770
Other external research and development (1)	6,911	12,340
Total external research and development expenses	27,244	38,310
Internal research and development expenses:		
Personnel related expenses	13,244	16,561
Total research and development expenses	$ 40,488	$ 54,871

(1) Chemistry manufacturing controls, research and preclinical studies and other miscellaneous expenses.

Exhibit 10.17

AMENDED AND RESTATED
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Effective September 27, 2024

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to AN2 Therapeutics, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Amended and Restated Non-Employee Director Compensation Policy for Board service effective as of the date first set forth above (the "***Effective Date***"). An Eligible Director may decline all or any portion of their compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy amends and restates the Non-Employee Director Compensation Policy previously adopted by the Board, is effective as of the Effective Date and may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
    a. All Eligible Directors: $40,000
    b. Non-Employee Chair of the Board: $30,000 (in addition to (a) above)
    c. Lead Independent Director: $25,000 (in addition to (a) above)
2. Annual Committee Chair Service Retainer:
    a. Chair of the Audit Committee: $15,000
    b. Chair of the Compensation Committee: $15,000
    c. Chair of the Nominating and Corporate Governance Committee: $8,000
3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):
    a. Member of the Audit Committee: $7,500
    b. Member of the Compensation Committee: $7,500
    c. Member of the Nominating and Corporate Governance Committee: $4,000

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2022 Equity Incentive Plan (the "***Plan***").

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board following the Effective Date, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a number of stock options ("***Options***") with a grant-date value of $209,093 (the "***Initial Grant***"). The Initial Grant Options will vest in substantially equal monthly installments through the first three years following the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date.

2. Annual Grants: On the date of each annual stockholder meeting of the Company held after the Effective Date, each Eligible Director who (x) has completed at least three months of Continuous Service as an Eligible Director as of the date of such annual stockholder meeting and (y) continues to serve as a non-employee member of the Board following such stockholder meeting will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted Options with a grant-date value of $104,546 (the "***Annual Grant***"); provided, however, that with respect to an Eligible Director who received an Initial Grant at least three, but less than six, months prior to the annual stockholder meeting date, such Eligible Director will be granted Options with a grant-date value of $52,273. The Annual Grant Options will vest in full on the earlier of (x) the one-year anniversary of the date of grant or (y) the day prior to the date of the Company's next annual stockholder meeting, subject to the Eligible Director's Continuous Service through such vesting date.

3. Accelerated Vesting: Notwithstanding the foregoing, each Initial Grant and each Annual Grant will vest in full upon a Change in Control (as defined in the Plan) prior to termination of such Eligible Director's Continuous Service.

Election to Receive Restricted Stock Units ("RSUs") In Lieu of Annual Retainers

General: The Board or its Compensation Committee (the "***Compensation Committee***") may, in its discretion, provide Non-Employee Directors with the opportunity to elect to convert all or a portion of their annual retainers into awards of RSUs ("***Retainer RSU Awards***") granted under the Plan or any other applicable Company equity incentive plan then-maintained by the Company, with each such Retainer RSU Award covering a number of shares of Common Stock calculated by dividing (i) the amount of the annual retainer that would have otherwise been paid to such Non-Employee Director on the applicable grant date by (ii) the average per share closing trading price of the Common Stock over the most recent 30 trading days as of the grant date (such election, a "***Retainer RSU Election***"), then multiplying the resulting number of shares by 1.1x.

Each Retainer RSU Award automatically will be granted on the tenth day of the month immediately following the end of the quarter for which the corresponding portion of the annual retainer was earned. Each Retainer RSU Award will be fully vested on the grant date.

Election Method: Each Retainer RSU Election must be submitted to the Company in the form and manner specified by the Board or the Compensation Committee. An individual who fails to make a timely Retainer RSU Election will not receive a Retainer RSU Award and instead will receive the applicable annual retainer in cash. Retainer RSU Elections must comply with the following timing requirements:

Initial Election. Each individual who first becomes a Non-Employee Director may make a Retainer RSU Election with respect to annual retainer payments scheduled to be paid in the same calendar year as such individual first becomes a Non-Employee Director (the "***Initial Retainer RSU Election***"). The Initial Retainer RSU Election must be submitted to the Company on or before the date that the individual first becomes a Non-Employee Director (the "***Initial Election Deadline***"), and the Initial Retainer RSU Election will become final and irrevocable as of the Initial Election Deadline.

Annual Election. No later than December 31 of each calendar year, or such other deadline as may be established by the Board or the Compensation Committee, in its discretion (the "***Annual Election Deadline***"), each individual who is a Non-Employee Director as of immediately before the Annual Election Deadline may make a Retainer RSU Election with respect to the annual retainer relating to services to be performed in the following calendar year (the "***Annual Retainer RSU Election***"). The Annual Retainer RSU Election must be submitted to the Company on or before the applicable Annual Election Deadline and will become effective and irrevocable as of the Annual Election Deadline.

Election to Defer Issuances

General: Each Non-Employee Director shall have the opportunity to defer the issuance of the shares underlying RSUs granted under this Program (including, for clarity, Retainer RSUs, Initial RSU Awards, the IPO RSU Awards and Annual RSU Awards) that would otherwise be issued to the Non-Employee Director in connection with the vesting or grant of the RSUs (including, for clarity, the Retainer RSU Awards, Initial RSU Awards, the IPO RSU Awards and Annual RSU Awards) until the earliest of a fixed date properly elected by the Non-Employee Director, the Non-Employee Director's Termination of Service or a Change in Control. Any such deferral election ("***Deferral Election***") shall be subject to such rules, conditions and procedures as shall be determined by the Board or the Compensation Committee, in its sole discretion, which rules, conditions and procedures shall at all times comply with the requirements of Section 409A of the Code, unless otherwise specifically determined by the Board or the Compensation Committee. If an individual elects to defer the delivery of the shares underlying RSUs granted under this Program, settlement of the deferred RSUs shall be made in accordance with the terms of the Deferral Election.

Election Method: Each Deferral Election must be submitted to the Company in the form and manner specified by the Board or the Compensation Committee. Deferral Elections must comply with the following timing requirements:

Initial Deferral Election. Each individual who first becomes a Non-Employee Director may make a Deferral Election with respect to the Non-Employee Director's RSUs to be granted in the same calendar year as such individual first becomes a Non-Employee Director (the "***Initial Deferral Election***"). The Initial Deferral Election must be submitted to the Company on or before the Initial Election Deadline, and the Initial Deferral Election shall become final and irrevocable as of the Initial Election Deadline.

Annual Deferral Election. No later than the Annual Election Deadline, each individual who is a Non-Employee Director as of immediately before the Annual Election Deadline may make a Deferral Election with respect to the RSUs to be granted in the following calendar year (the "***Annual Deferral Election***"). The Annual Deferral Election must be submitted to the Company on or before the applicable Annual Election Deadline and shall become final and irrevocable for the subsequent calendar year as of the applicable Annual Election Deadline.

No portion of an IPO RSU Award, Initial RSU Award or Annual RSU Award which is unvested at the time of a Non-Employee Director's termination of service on the Board will become vested and exercisable thereafter.

Expenses

The Company will reimburse Eligible Directors for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; provided, that the Eligible Director timely submit to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

Exhibit 10.18

EXCLUSIVE PATENT LICENSE AGREEMENT

This Exclusive Patent License Agreement, effective as of October 10, 2023 ("Effective Date"), is entered by and between the **University of Georgia Research Foundation, Inc.**, a Georgia non-profit corporation **("UGARF")**, and **AN2 Therapeutics, Inc.**, a Delaware corporation having a principal place of business at 1800 El Camino Real, Suite D, Menlo Park, CA 94027 **("Licensee")**. UGARF and Licensee may each be referred to individually as a "Party" or may together be referred to collectively as the "Parties."

A. The Wellcome Trust Limited as trustee of The Wellcome Trust (the "Trust"), Anacor Pharmaceuticals ("Anacor"), and UGARF are parties to that Not-For-Profit Funding Agreement (Seeding Drug Discovery) dated October 15, 2014, as amended by the First Amendment dated February 20, 2017, the Notice and Amendment No. 2 dated April 17, 2020, the Third Amendment dated December 3, 2020, the Fourth Amendment dated April 21, 2021, and the Fifth Amendment dated on or about May 11, 2022 (collectively, with any additional future amendments, the "Anacor License Agreement"). A true and complete copy of the Anacor License Agreement is attached hereto as Schedule 1.1. AN2 shall treat the Anacor License Agreement as UGARF Confidential Information.

B. Pursuant to the Anacor License Agreement:

   1. Trust, Anacor, and UGARF funded and/or performed, and are continuing to fund and/or perform, certain research.

   2. Anacor is the owner of certain materials resulting from the research, including Project Compounds (as defined by the Anacor License Agreement) and intellectual property rights therein, which are included among Project Intellectual Property (as defined by the Anacor License Agreement).

   3. Trust, Anacor, and UGARF have agreed that UGARF is the Exploiting Party (as defined by the Anacor License Agreement) responsible for patent prosecution and maintenance, as well as commercialization, of Project Compounds and associated Project Intellectual Property.

   4. Anacor has granted to UGARF an exclusive, even as to Anacor (but subject to certain Anacor reserved rights), right and license to those Project Intellectual Property rights in and to Project Compounds with the right to sublicense the rights to have made, use, have used, have sold, offer to sell, import, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized, and otherwise exploit Project Compounds in Field B within the Territory and to otherwise exploit Project Compounds and Products in Field B within in the Territory (with each such capitalized term not defined in this Agreement having the meaning given to it by the Anacor License Agreement).

   5. In any such sublicense, UGARF is required to flow certain terms to sublicensees, including Licensee herein.

C. The Licensed Patents that are the subject of this Agreement relate to the use of small molecule therapeutics for the treatment of Chagas disease, are designated by UGARF with the reference Case No. 2019-145 titled "Oxaborole Esters and Uses Thereof," relate to Project Compounds, and are included within Project Intellectual Property.

D. UGARF desires to have the Licensed Patents commercialized, and Licensee wishes to obtain the right to use the Licensed Patents for commercial purposes and represents that it has the necessary expertise and has or will acquire the necessary resources to do so.

THEREFORE, in exchange for the mutual promises set out in this Agreement and other due and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows.

ARTICLE 1DEFINITIONS

1.1 **"Affiliate"** means, with respect to any entity, any person that, on the Effective Date or during the Term, controls, is controlled by, or is under the common control with such entity. For the purposes of this definition: (a) "control" means (i) the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of an entity, whether through the ownership of voting securities or other ownership interest, by contract or otherwise or (ii) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities or other ownership interest of the entity; and (b) "person" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority, or any other form of entity not specifically listed herein.

1.2 **"Confidential Information"** means any and all data, results, Know-How (as defined by the Anacor License Agreement), show how, software, plans, details of research work, discoveries, inventions, intended publications, intended or pending patent applications, designs, technical information, business plans, budgets and strategies, business or financial information, or other information in any medium and in any form, and any physical items, prototypes, compounds, samples, components, or other articles or Materials (as defined in the Anacor License Agreement) disclosed on or after the Effective Date by one Party to the other Party whether orally or in writing or in any other form; and without limiting the breadth of the foregoing UGARF's Confidential Information specifically includes the Anacor License Agreement and its terms, this Agreement and its terms, as well as any and all other information that contains or makes reference to any one or more of the following: inventions; patent applications; intellectual property holdings or strategy; know-how; source code or software; data, biological or chemical materials; prototypes or devices; product development information and market efforts; financial information; sales information; Progress Reports; Royalty Reports; Sublicensee Fee Reports; customer, Sublicense, or Sublicensee information; business or legal arrangements; tax filings; and/or information related to actual or potential litigation.

1.3 **"Contractor"** means a third-party to which Licensee or a Sublicensee has granted Production Rights.

1.4 **"Licensed Field"** means the therapeutic, diagnostic, and prophylactic treatment of Chagas disease in humans or animals.

1.5 **"Licensed Patent Expenses**" means all costs incurred and/or paid by UGARF with respect to the filing, prosecution, maintenance, defense against interference, and/or extension of the term of Licensed Patents in the Licensed Patent Territory.

1.6 "**Licensed Patents**" means the issued patents and patent applications identified at Appendix A as well as any patents that issue therefrom.

1.7 "**Licensed Product**" means any product, service, or process in the Licensed Field, the manufacture, use, and/or sale of which at the time of any such manufacture, use, delivery, and/or sale, absent the licenses granted under this Agreement, would infringe one or more Valid Claims.

1.8 "**Licensed Product Sales"** means all accrued consideration received in exchange for the sale or other transfer of Licensed Products to a third-party but does not include **[***]**

1.9 **"Licensed Patent Territory"** means, for each Licensed Patent, the territories in which there exists at least one Valid Claim of that Licensed Patent.

1.10 **"Licensed Territory"** means worldwide.

1.11 **"Production Rights"** means the limited right and license to practice one or more Licensed Patents, in the respective Licensed Patent Territory for the sole purposes of: (a) developing and/or manufacturing Licensed Products; and/or (b) transferring, delivering, importing, exporting and/or selling Licensed Products to only Licensee and/or Sublicensees but not to third-party purchasers; and/or (c) offering for sale and/or selling Licensed Products in the name of, and on behalf of, Licensee and/or Sublicensees.

1.12 **"Production Rights Agreement"** means an agreement between Licensee or a Sublicensee, and a third-party, in which Licensee or Sublicensee grants to such third-party, either alone or with other rights, some or all Production Rights.

1.13 **"Sublicense"** means a sublicense between Licensee and a third-party in which Licensee grants to such third-party, either alone or with other rights, any or all of the rights to make, have made, use, import, export, offer for sale and sell Licensed Products in the third-party's name.

1.14 **"Sublicense Fee"** means any and all cash consideration and/or the value of any and all equity received by Licensee in exchange for the grant of a Sublicense, but excluding sales-based royalty payment amounts received by Licensee from any one or more Sublicensees based on and for the sale of Licensed Products. For clarity, investment by a Sublicensee in equity of Licensee as part of a larger bona fide financing transaction of at least twice the amount of equity purchased by such Sublicensee on the same terms as other purchasers of Licensee equity shall not be considered a Sublicensee Fee payment.

1.15 **"Sublicensee"** means a third-party to which Licensee has granted a Sublicense.

1.16 "**Valid Claim**" means a claim in any (a) issued and unexpired patent included among the Licensed Patents, so long as such claim has not have been irrevocably abandoned or held invalid in an unappealable decision of a court or other authority of competent jurisdiction; and (b) a claim of a pending patent application included among the Licensed Patents that has been pending for no more than **[***]** since its earliest priority date, which claim was filed in good faith and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

ARTICLE 2GRANT OF LICENSE

2.1 **Grant of Rights**. Subject to the reservations, retained rights, payment obligations, and other terms of this Agreement, UGARF grants to Licensee the exclusive right and license in the Licensed Territory to practice each Licensed Patent in its Licensed Patent Territory only as necessary to make, use, import, offer for sale, and sell (including the right to commercialize) Licensed Products. The grant of rights in this Section 2.1 includes the right to Sublicense and grant Production Rights in accordance with Sections 2.2 and 2.3.

2.2 **Production Rights.** Licensee may grant Production Rights to Contractors in Production Rights Agreements without UGARF's prior approval. Licensee shall provide UGARF with a copy of each and every Production Rights Agreement that Licensee or any Sublicensee has in place with any Contractor within 15 days of its execution. Any copy may be redacted for confidential information of third-parties and other license rights with respect to other products and technology that are not Licensed Products. Licensee must include in every Production Rights Agreement all terms required in Sublicenses per Section 2.3 adjusted to requirements of Contractors under Production Rights Agreements. Licensee shall remain fully responsible to UGARF for those operations of each Contractor that are relevant to this Agreement as if such operations were carried out by Licensee. A breach by a Contractor of any terms required of Licensee or Contractor hereunder or otherwise by this Agreement shall be considered a breach of this Agreement by Licensee.

2.3 **Sublicensing.** UGARF grants to Licensee the right to enter into one or more Sublicenses having terms consistent with this Agreement, but Licensee may not grant to any Sublicensee the right to grant sub-sublicenses of any rights in or to Licensed Patents or Licensed Products except that Licensee may grant to any one or more Sublicensees the right of such Sublicensee to grant Production Rights to Contractors. Licensee must comply with all of the following requirements with respect to any and all Sublicenses.

2.3.1 Copy of Sublicenses. Licensee shall provide UGARF with an unredacted copy of any Sublicense within **[***]** after its execution sufficient for UGARF to verify compliance with the terms of the Agreement, including financial obligations, provided that the unredacted copy shall be maintained as confidential information of Licensee.

2.3.2 Copy of Sublicense Payment Reports. Licensee shall provide UGARF with an unredacted copy of each report related to Licensed Patents and/or Licensed Products received by Licensee from each Sublicensee to the extent related to payments to UGARF pursuant to Article 4 hereunder.

2.3.3 Responsibility for Sublicensees. Licensee shall remain fully responsible to UGARF for those operations of each Sublicensee that are relevant to this Agreement as if such operations were carried out by Licensee. A breach by a Sublicensee of any terms required of the Sublicensee by this Agreement, or that Licensee is required to flow to Sublicensee in a Sublicense, shall be considered a breach of this Agreement by Licensee.

2.3.4 Sublicensee Indemnification Obligation to UGARF. Licensee must include in each Sublicense a provision requiring the Sublicensee(s) to indemnify, defend, and hold UGARF and all Indemnitees (as defined in Section 9.4) harmless from and against claims and damages asserted or assessed against UGARF related to a Sublicensee's operations to the same extent Licensee is so required.

2.3.5 Sublicensee Insurance Requirements. Licensee must include a provision in each Sublicense requiring the Sublicensee to maintain insurance coverage to materially same extent that Licensee is so required under this Agreement.

2.3.6 Sublicense Audit Requirements. Licensee must include a provision in each Sublicense requiring the Sublicensee to permit access to, and the right for Licensee to conduct an inspection and audit of Sublicensee on behalf of UGARF upon prior written notice to Licensee, to the same extent Licensee is so required to make its facilities, books, and records, available to UGARF under this Agreement. To the extent that Licensee conducts such inspection and audit, UGARF shall be invited, under appropriate confidentiality obligations, to participate with Licensee in the conduct of such inspection and audit.

2.3.7 Required Anacor Terms. Licensee must include a provision in each Sublicense requiring that Anacor is a third-party beneficiary of the Sublicense with the right to enforce Licensee's and the Sublicensee's obligations to Anacor as are required of Licensee herein, including but not limited to those obligations to Anacor in Section 2.5. (Anacor Retained Rights); Sections 9.5.1. and 9.5.2. (Indemnification); Section 11.6.1 (Use of Names); Section11.6.2 (Press Release); Section 9.6 (Insurance); and Section 11.14 (Third-Party Beneficiary) of this Agreement.

2.4 **UGARF Reservation of Rights.** The rights and licenses granted in this Article 2 are subject to a reserved non-exclusive, non-sublicensable, non-transferable right for UGARF to use Licensed Patents for the limited purposes of its own internal academic research and that of its academic collaborators including but not limited to the University of Georgia, provided that such research is not carried out in collaboration with or for the benefit of any commercial third-party. Rights not expressly granted to Licensee or reserved for UGARF, the University of Georgia, or any third-party hereunder are hereby reserved to UGARF.

2.5 **Anacor Retained Rights.** Licensee acknowledges and agrees that the rights and licenses granted in this Article 2 are also subject to the following retained rights: (a) Anacor retains the right to make, have made, use, and import the Project Compound and Product and to use the Project Intellectual Property solely for all research and development purposes, excluding (i) the use of any Project Compound in any clinical trial directed to developing any Project Compound and (ii) commercializing or having commercialized any Project Compound, and (b) Anacor is free to use the Licensed Patent Rights for purposes other than those exclusively licensed to Exploiting Party under this Agreement. Notwithstanding anything to the contrary in this Agreement, nothing herein shall be deemed to prevent or restrict in any way the ability of Anacor or its Affiliates to conduct any activities in the Territory, which activities would be allowed under any safe harbor, research exemption, government, or executive declaration of urgent public health need, or similar right available in law or in equity if conducted by a Third Party.

2.6 **Trust Reservation of Rights.** Licensee acknowledges and agrees that the rights and licenses granted in this Article 2 are further subject to the reserved rights for Trust to practice Licensed Patents for research, development, regulatory purposes.

2.7 **Global Social Responsibility.** In performing the activities contemplated under this Agreement, the Parties agree to take into consideration the principle of "Global Social Responsibility," which is defined to mean facilitating the availability of Licensed Products in "Developing Countries" in the Licensed Territory at locally affordable prices, under reasonable circumstances and terms to improve access to such Licensed Products in such countries. "Developing Counties" is defined to mean those counties in the Licensed Territory that are listed by the World Bank as "Low-Income Economies," as such list may change from time to time. Solely by way of example, in support of a Party's Global Social Responsibility the Parties may mutually agree to revise royalty rates, adjust fair market value, consider non-monetary consideration, and/or develop targeted patent strategies.

ARTICLE 3DILIGENCE

3.1 **Reasonable Commercial Diligence.** Licensee shall use commercially reasonable efforts, directly and/or through operations of its Contractors and/or Sublicensees, to bring Licensed Products to market, and to create, supply, and service throughout each Licensed Patent Territory. Licensee's failure to meet the requirements of this Section 3.1 is a material breach of this Agreement.

3.2 **Specific Diligence, Development, and Sales Requirements.** Licensee shall use commercially reasonable efforts to attain each development milestone event, sales milestone event, and all other milestone events, each of which is identified in Appendix B (each, a "Milestone") on or before the corresponding deadline for each milestone specified. In the event that Licensee is unable to achieve a milestone event by the date specified, Licensee and UGARF shall meet and discuss the reason for such failure. In the event that UGARF and Licensee are unable to reach agreement on an adjustment or extension of the milestone event within **[***]** of the failure date, then Licensee's failure to meet any one or more Milestones by the applicable due date shall be a material breach of this Agreement.

3.3 **Patent Marking.** Licensee and each Sublicensee shall place in a conspicuous location on all Licensed Products (or on their packaging and accompanying written materials where appropriate) a patent notice regarding the applicable Licensed Patents in accordance with applicable law.

ARTICLE 4PAYMENTS

4.1 **Initial License Fee**. As a condition to the rights granted in this Agreement, including Article 2, Licensee shall within **[***]** of the Effective Date deliver to UGARF a non-refundable payment in the amount of **[***]** ("Initial License Fee"). This Agreement will terminate automatically without any additional notice required in the event that Licensee has not delivered to UGARF payment of the Initial License Fee by its due date. With its payment, Licensee shall indicate that this payment represents the Initial License Fee.

4.2 **License Maintenance Fees.** Each year, beginning **[***]** and no later than each **[***]** thereafter until initiation of the first clinical trial of the first Licensed Product, Licensee shall deliver to UGARF a non-refundable payment in the amount of **[***]** ("Maintenance Fee"). With each such payment, Licensee shall indicate that the payment represents a Maintenance Fee.

4.3 **Milestone Fees.** Licensee shall deliver to UGARF each payment related to a Milestone as required by Appendix B (each a "Milestone Fee") within **[***]** of the close of the calendar quarter in which the corresponding Milestone was achieved or by any due date identified for such Milestone on Appendix B, whichever is earlier. With each Milestone Fee payment, Licensee shall indicate the specific Milestone achieved. Each Milestone Fee payment shall be payable only once on the first achievement per product of the Milestone set forth on Appendix B.

4.4 **Royalty Payments**. For each calendar quarter, Licensee shall deliver to UGARF a running royalty payment equal to **[***]** of all Licensed Product Sales, subject to deductions for Stacked Royalties as permitted below, received directly by, or on behalf of, Licensee and all Sublicensees in such quarter ("Royalty Payment"). Licensee shall deliver its quarterly Royalty Payment to UGARF for a particular calendar quarter no later than the corresponding Royalty Payment Due Date identified in the table below that immediately follows the close of such calendar quarter.

Licensed Product Sales in the Calendar Quarter	**Royalty Payment Due Date**
January 1 – March 31	**[***]**
April 1 – June 30	**[***]**
July 1 – September 30	**[***]**
October 1 – December 31	**[***]**

However, the Parties acknowledge that, in order to offer to sell and/or sell a particular Licensed Product absent infringement of third-party patent rights, Licensee and/or Sublicensees may be required to license patent rights from third-parties ("Third-Party Patent License"), and license of those patent rights may require Licensee and/or Sublicensee to pay royalties calculated as a percentage of Licensed Product sales to such third-parties ("Stacked Royalties"). If, in any particular calendar quarter, one or more Third-Party Patent Licenses was required to enable Licensee and/or Sublicensees to offer for sale and/or sell any particular Licensed Product in such quarter without infringing third-party patent rights, then Licensee may deduct from the total Licensed Product Sales in such calendar quarter associated with such Licensed Product the amount of any Stacked Royalties paid by Licensee and/or Sublicensees for such quarter as consideration for those Third-Party Patent Licenses absent which the offer for sale or sale of such Licensed Product in the quarter would have infringed third-party patent rights; *except that* Stacked Royalties for a particular Licensed Product in any particular calendar quarter are capped at an amount equal to half of the associated Licensed Product Sales for such Licensed Product in the calendar quarter, such that, as a result of the application of Stacked Royalties, Licensed Product Sales for a particular Licensed Product in a particular calendar quarter may never be reduced by more than **[***]** (i.e., reduction floor of royalty to UGARF of not less than **[***]** for all applicable Stacked Royalties) for the purpose of computing the Royalty Payment due to UGARF associated with such Licensed Product Sales. In the event that Licensee intends to deduct any Stacked Royalties from any Licensed Product Sales in a particular calendar quarter, then in the Royalty Report for such quarter due per Section 5.2 Licensee shall identify the third-party patent payments associated with all such Stacked Royalties, as well as the third-parties from which they were licensed and the owner of the third-party rights (if different), providing sufficient detail to allow UGARF to confirm that the deduction of Stacked Royalties is appropriate.

4.5 **Sublicense Fee Payments.** No later than **[***]** after the calendar quarter in which Licensee receives any Sublicense Fee, Licensee shall deliver to UGARF a payment computed as a percentage of such Sublicense Fee as determined by the applicable Technology Development Stage per the table at Appendix C (each, a "Sublicense Fee Payment").

Sublicense Fee Received in the Calendar Quarter	**Sublicense Fee Payments Due Date**
January 1 – March 31	**[***]**
April 1 – June 30	**[***]**
July 1 – September 30	**[***]**
October 1 – December 31	**[***]**

4.6 **Priority Review Voucher Fee Payments.** No later than **[***]** after the calendar quarter in which consideration is received by Licensee or Sublicensee upon the transfer of a Priority Review Voucher received as a result of approval of a Licensed Product Licensee or Sublicensee receives consideration for the sale or transfer of a Priority Review Voucher, Licensee shall deliver to UGARF a payment in the amount as required in Appendix D of all such consideration (a "PRV Fee Payment").

4.7 **Taxes.** All payments to UGARF will be made free and clear of any tax, customs, or other governmental charge or levy ("Taxes"). If Licensee is obligated by law to withhold Taxes on any payments to UGARF, Licensee shall be entitled to deduct the applicable withholding amount with respect to such payment, provided that Licensee separately documents the applicable withholding requirements and amounts.

4.8 **Making Payments and Wire Fee.** All payments due to UGARF under this Agreement shall be made either by wire transfer to an account designated by UGARF in Appendix E (or to a different account identified from time to time by UGARF upon notice to Licensee) or by check delivered to **[***]**. For each payment made by wire transfer, to the extent UGARF is charged for receipt of such wire, UGARF shall separately invoice Licensee, and Licensee shall pay the applicable additional fee of **[***]** for payments originating from a domestic U.S. account or **[***]** for payments originating from a foreign account. UGARF will not provide invoices to Licensee or any Sublicensee for any payments due under this Agreement except with respect to the reimbursement of Patent Expenses, and it is Licensee's responsibility to ensure that all payments owed to UGARF under this Agreement are received by UGARF when due.

4.9 **Currency Conversion.** All payments to UGARF shall be paid in U.S. Dollars. If any Licensed Product Sales or Sublicensee Fees are made in a currency other than U.S. Dollars, then the associated amount owed to UGARF shall first be determined in the currency received by Licensee and/or the Sublicensee and then converted to U.S. Dollars at the rate for conversion of the foreign currency into U.S. Dollars as published by the Wall Street Journal (U.S. ed.) on the day the corresponding payment is due.

4.10 **Overdue Payments**. All overdue payments under this Agreement shall bear simple interest until paid at the lower of the annual rate of **[***]** or the highest rate permitted by law. Interest accruing under this section shall be due UGARF automatically without demand.

4.11 **No Refunds or Credits**. All amounts paid to UGARF pursuant to this Agreement shall be non-refundable, and no amount paid to UGARF shall be credited against any other amount due by Licensee under this Agreement or any other agreement**.**

4.12 **Full Payment of Amounts Owed.** UGARF shall be solely and fully responsible for the timely and complete payment of any and all of UGARF's payment obligations to Anacor or any third-party under the Anacor License Agreement related to the rights granted to Licensee pursuant to this Agreement.

ARTICLE 5REPORTS AND RECORDS INSPECTION

5.1 **Progress Reports.** Each year, no later than **[***]** for the prior calendar year, Licensee shall deliver to UGARF a written report containing the information identified for Progress Reports at Appendix

D detailing the current progress of the Licensee, directly and through the work of Sublicensees and Contractors, toward the development and commercialization of Licensed Products throughout each of the Licensed Patent Territories (each, a "Progress Report"). Licensee shall identify in each Progress Report all Milestones attained, and all Milestone Fees due and/or paid, in the calendar year being reported.

5.2 **Royalty Reports.** Four times per calendar year, once for each calendar quarter, Licensee shall deliver to UGARF a written report containing the information identified for Royalty Reports at Appendix D for Licensed Product Sales in such calendar quarter (each, a "Royalty Report"). Licensee shall deliver a Royalty Report to UGARF on the same schedule as Royalty Payments; specifically, the Royalty Report corresponding to Licensed Product Sales for a particular calendar quarter is due within **[***]** after the close of such quarter.

Licensed Product Sales and Royalty Fees Due for the Calendar Quarter	**Royalty Report Due Date**
January 1 – March 31	**[***]**
April 1 – June 30	**[***]**
July 1 – September 30	**[***]**
October 1 – December 31	**[***]**

5.3 **Sublicense Fee Reports.** For each calendar quarter in which Licensee receives one or more Sublicensee Fees, Licensee shall deliver to UGARF a report identifying the nature and amount of the Sublicensee Fee, the name of the Sublicensee that paid the Sublicensee Fee and the transaction(s) to which it relates, as well as the corresponding Sublicense Fee Payment due under this Agreement and the dates due and paid.

5.4 **Recordkeeping**. Licensee shall keep, and shall cause Sublicensees to keep, accurate records in sufficient and customary detail such that the amounts due under this Agreement, and full compliance with this Agreement, may be verified.

5.5 **Records Inspection.** During the term of this Agreement and for a period of **[***]** after any payment made to UGARF pursuant to this Agreement, Licensee shall permit UGARF or its representatives, to inspect, review, analyze, and copy, Licensee's books and records regarding the manufacture and sale of Licensed Products, the completeness of Progress Reports, Royalty Reports, Sublicense Fee Reports, and diligence efforts (each, a "Records Inspection"). Such books and records shall include, to the extent applicable to Licensee for, but are not limited to invoice registers and original invoices; product sales reports; price lists, accounting general ledgers; Sublicenses, Production Rights Agreements, and distributor agreements; financial statements and income tax returns; sales tax returns; inventory and production records; and shipping documents. UGARF or its representatives may conduct a Records Inspection no more than once per calendar year, and any Records Inspection may relate to any one or more years in any given **[***]** period under this License Agreement at UGARF's discretion. Upon UGARF's notice to Licensee of an intended Records Inspection, Licensee shall reasonably cooperate with UGARF in setting a mutually convenient time and place for such, ordinarily during regular business hours. Any Records Inspection shall be made at UGARF's expense, except that if a Records Inspection discloses a shortage of **[***]**, between the payments due UGARF for any calendar year or the final, partial year of this Agreement and the amounts actually paid by Licensee for such period, or if the Records Inspection reveals a material breach of this Agreement, then Licensee shall reimburse UGARF for its incurred costs, including professional fees, of such Records Inspection. **[***]**

ARTICLE 6LICENSED PATENT FILINGS, PROSECUTION, AND MAINTENANCE

6.1 **Prosecution and Maintenance**. Licensee acknowledges that Anacor is the owner and assignee of the Licensed Patents, but pursuant to the Anacor License Agreement, UGARF shall manage the prosecution and maintenance those Licensed Patents identified at Exhibit A as well as all other Licensed Patents in the Licensed Patent Territory elected by Licensee per Section 6.2 below. UGARF shall provide Licensee with copies of all filings and correspondence pertaining to such activities reasonably in advance of any deadlines so as to give Licensee reasonable opportunities to advise and cooperate with UGARF, and UGARF shall reasonably consider any advice and recommendations offered in proceeding with the prosecution and maintenance.

6.2 **Licensee Election of Additional Filings**. No later than **[***]** prior to the applicable application deadline for each, Licensee timely shall notify UGARF in writing of the territories in which Licensee elects for patent applications to be filed in the Licensed Territory, including but not limited to national phase filings and registrations in countries from regional filings. UGARF shall file such additional applications as permitted by the patent rules of the applicable jurisdiction, and these applications and resulting patents shall be included in the definition of Licensed Patents and the grant of rights made by this Agreement. UGARF shall update Appendix A by notice to Licensee to reflect new patent applications and patents as needed. For any territories not elected by Licensee by the due date indicated above, Licensee may later request that associated patent applications be filed and added to the scope of this Agreement, and in the event those applications are still available and UGARF and Licensee jointly agree to pursue to those applications, then they may be added to the scope of the Licensed Patents under this Agreement. UGARF shall update Appendix A by notice to Licensee to reflect new patent applications as needed.

6.3 **Licensee Election to Remove Licensed Patents.** By **[***]** prior written notice, Licensee may elect to remove any one or more applications and/or patents from the Licensed Patents and grant of rights under this Agreement. After such **[***]** period, the identified applications and/or patents shall automatically be removed from the definition of Licensed Patents and the grant of rights hereunder. UGARF shall update Appendix A by notice to Licensee to reflect the removal of patent applications and/or patents as needed. UGARF may elect to continue prosecution and/or maintenance of these patent applications and/or patents at its own expense or may permit them to be abandoned or lapse or prosecuted/maintained by third-parties.

6.4 **Patent Extensions.** By at least **[***]** notice to UGARF before the expiration of any particular Licensed Patent, Licensee timely may notify UGARF of the territories in which Licensee elects to apply to have the regular term of any Licensed Patent extended or restored under applicable procedure. Upon timely notice, UGARF shall file such applications for extension or restoration as permitted by applicable procedure, and any resulting patents and/or extended terms shall be included within the definition of Licensed Patents and the grant of rights made by this Agreement. For the avoidance of doubt, Licensee shall be obligated to make all payments due under this Agreement, and otherwise fully comply with this Agreement, through the end of the extended term of any Licensed Patent. UGARF shall update Appendix A by notice to Licensee to reflect new applications, patents, and/or extensions as needed.

6.5 **UGARF Separate Filings.** UGARF or third-parties may, at their own expense, file patent applications or applications for extension or restoration of Licensed Patents, in those territories in the Licensed Territory in which Licensee does not elect timely to do so per the terms of this Agreement. In that case, the resulting patents, including restored patents or patent rights during any such extension, shall not be included in the definition of Licensed Patents or the scope of any licenses granted herein.

6.6 **Licensee Reimbursement of Patent Expenses.** As of the Effective Date, current unreimbursed Patent Expenses total approximately **[***]**. Licensee shall reimburse UGARF for all unreimbursed Patent Expenses as incurred both before and after the Effective Date by delivering payments (each, a “Patent Expense Reimbursement Payment”) to UGARF as follows:

6.6.1For the four-year period beginning **[***]** and ending **[***]**, no later than **[***]** after the close of each calendar quarter within the period, Licensee shall deliver payment to UGARF in the amount of **[***]** to be applied toward unreimbursed Patent Expenses. A total of **[***]** quarterly payments, totaling **[***]**, are due for this four-year period; these amounts are due by Licensee per the terms of this Agreement, and UGARF will not send an invoice to Licensee for such amounts.

6.6.2On or about **[***]**, UGARF shall invoice Licensee of the total of all remaining unreimbursed Patent Expenses as of **[***]**, and Licensee shall deliver payment to UGARF for unreimbursed Patent Expenses in the amount identified on the invoice within **[***]** of UGARF's invoice date for such.

6.6.3After UGARF's invoice per Section 6.6.2, UGARF shall thereafter invoice Licensee for reimbursement of any additional unreimbursed Patent Expenses from time to time, and Licensee shall reimburse UGARF by delivering reimbursement payments to UGARF in the amount of each invoice within **[***]** of UGARF's invoice date for such.

It is a material breach of this Agreement for Licensee to fail to make any Patent Expense Reimbursement when due.

6.7 **Removal for Failure to Make Patent Expense Reimbursements**. If Licensee is more than 180 days overdue in making any Patent Expense Reimbursement when due per Section 6.6 with respect to any Patent Expenses for any one or more particular Licensed Patents, then UGARF, in addition to its other remedies under this Agreement, may by 60 days' notice to Licensee remove such Licensed Patents identified in the notice from the definition of Licensed Patents and the grant of rights hereunder. UGARF shall update Appendix A by notice to Licensee to reflect the removal of patent filings and/or patents as needed.

6.8 **UGARF Discretion after Removal of Licensed Patents.** If for any reason any one or more patents and/or patent applications is removed from the definition of Licensed Patents and the scope of this Agreement, and/or if for any reason Licensee does not timely elect by the due dates set out in this Agreement for UGARF to file any particular patent application, maintain any particular patent, and/or file for any patent extension, then thereafter UGARF shall have no obligation whatsoever to Licensee, any Sublicensee, or any Contractor with respect to such patents, patent applications, and any attendant rights, which UGARF may pursue, abandon, license to one or more other entities, or otherwise commercialize and/or dispose of in UGARF's sole discretion.

6.9 **Anacor Retained Rights.** Notwithstanding anything to the contrary herein, Licensee acknowledges and agrees that: Anacor, as the owner of Licensed Patents, may in its discretion choose not to take any action in connection with the prosecution of the Licensed Patents that Anacor reasonably believes would be likely to materially adversely affect Anacor's other patent applications or patents or exploitation of the Non-Project Compounds or Background Intellectual Property (as those terms are defined by the Anacor License Agreement) outside of Chagas disease; and UGARF shall have no liability to Licensee or any of its Sublicensees or Contractors in the event Anacor exercises any rights described herein.

ARTICLE 7INFRINGEMENT

7.1 **Possible Infringement and Enforcement.** Each of Licensee and UGARF shall report timely to the other Party all suspected infringement of any one or more Licensed Patents of which UGARF, Licensee, or any Sublicensee or Contractor becomes aware. It is a material breach of this Agreement by Licensee for Licensee or any Sublicensee or Contractor to contact any third-party suspected of infringement of any one or more Licensed Patents without the prior express written permission of UGARF. If either Party desires to file suit against an alleged infringer of one or more Licensed Patents, then such Party promptly shall notify the other, and the Parties shall discuss and coordinate enforcement efforts as provided in this Article 7.

7.2 **Licensee Enforcement.** If Licensee desires to assert one or more infringement claims and/or file suit against an alleged infringer of one or more Licensed Patents in its Licensed Patent Territory, then Licensee shall so notify UGARF. If and only if UGARF authorizes, in UGARF's sole discretion, Licensee to proceed, then Licensee may initiate claims and/or suit following discussion between the Parties. UGARF shall cooperate with Licensee in all reasonable respects regarding the claims in relating to any litigation, and UGARF acknowledges and agrees that it shall give its consent to be added as a party to any authorized suit if UGARF is determined to be a necessary party. Licensee shall have the sole authority to undertake, negotiate, and settle the matter in any manner consistent with the rights granted to Licensee herein and so long as such settlement does not reduce or negatively impact UGARF's rights in any material manner. Licensee shall employ counsel reasonably satisfactory to UGARF to represent the interests of Licensee. Licensee shall provide UGARF with copies of all material correspondence and pleadings. Licensee's counsel shall also represent UGARF with respect to all authorized claims, attendant claims asserted by, and any related claims asserted against UGARF. Licensee shall be responsible for all costs of the matter including but not limited to all costs of litigation, including representation of UGARF by Licensee's counsel. UGARF may also be represented by its own counsel at UGARF's expense. Recoveries, including but not limited to settlements and any amounts paid on judgments, collected by or on behalf of Licensee and/or UGARF related to any of the foregoing (i) will be paid to Licensee and to UGARF to reimburse their expenses incurred in such matter (and if the recovery is not sufficient to reimburse both Parties for all expenses, then the Parties will be reimbursed proportionately based on their individual expenses incurred), and then **[***]**.

7.3 **UGARF Enforcement.** If Licensee does not desire or is not authorized to assert one or more infringement claims and/or file suit against an alleged infringer of one or more Licensed Patents in its Licensed Patent Territory, then UGARF may do so. Licensee shall cooperate with UGARF in all reasonable respects in the matter, and Licensee acknowledges and agrees that it shall reasonably consent to be added as a party to any related suit if Licensee is determined to be a necessary party. As between UGARF and Licensee, UGARF shall have the sole authority to undertake, negotiate, and settle the matter in any manner without limitation. UGARF has the right to grant and may grant non-exclusive licenses in settlement of any such enforcement claims or action initiated hereunder, thereby reducing the exclusivity of the license granted to Licensee herein, provided that UGARF shall not grant any such sublicense to a direct competitor of Licensee unless at least one other direct competitor is already, or has been, a Sublicensee. UGARF shall employ counsel of its own choosing in the matter, and Licensee if required to be added to the suit may be represented by UGARF's counsel, or counsel of Licensee's own choosing, in the latter case at Licensee's expense. UGARF shall be responsible for all of its own related expenses. Recoveries, including but not limited to settlements and any amounts paid on judgments, collected by or on behalf of UGARF and/or Licensee related to any of the foregoing (i) will be paid to UGARF and to Licensee to reimburse their expenses incurred in such matter (and if the recovery is not sufficient to reimburse both Parties for all expenses, then the Parties will be reimbursed proportionately based on their individual expenses incurred), and then **[***]**.

7.4 **Abandonment.** If either Party commences any claim or suit against an alleged infringer of one or more Licensed Patents in its Licensed Patent Territory and thereafter elects to abandon such claim or suit, the abandoning Party shall give timely notice to the other Party, which may continue prosecution of such claims and/or suit or otherwise manage the matter in its discretion so long as the Parties first reach an agreement for sharing recoveries and expenses.

ARTICLE 8CONFIDENTIALITY

8.1 **Limited Exchange of Confidential Information.** The Parties intend to exchange Confidential Information between them under this Agreement. The "Provider" of Confidential Information is the Party that possesses and then discloses or otherwise provides Confidential Information to the other Party to this Agreement, and the "Recipient" of Confidential Information is the Party receiving it from the Provider. The Parties agree they will only exchange Confidential Information under this Agreement as necessary to fulfill the material purpose of this Agreement and their obligations hereunder.

8.2 **Non-Disclosure of Confidential Information.** Except to the extent required by law and subject to Sections 8.3 through 8.5 below, beginning on the Effective Date and extending for the later of (a) **[***]** after termination of the Anacor License Agreement or (b) **[***]** after all rights in Licensed Patents granted to Licensee hereunder have either expired, been removed from the scope of this Agreement, or have otherwise terminated, a Recipient of the Provider's Confidential Information shall not disclose and shall take all reasonable security precautions to keep confidential and not disclose such Confidential Information to any person other than to the Recipient's officers, employees, or professional advisors who need to know such Confidential Information strictly for the purposes of this Agreement, and they shall use such Confidential Information only as necessary for performance of this Agreement. Licensee may receive information under this Agreement that is the Confidential Information (as defined by the Anacor License Agreement) of Trust or Anacor, and in those cases, Licensee shall protect such information and limit its use and disclosure to the full extent required by the Anacor License Agreement, including Article 14 therein, if inconsistent with this Agreement. Licensee agrees that it will abide by all obligations of confidentiality, use, and disclosure of information required of UGARF by the Anacor License Agreement.

8.3 **Exception for Disclosure to Third-Party Recipients.** Notwithstanding anything to the contrary herein, a Recipient may disclose the Provider's Confidential Information to those affiliates, agents, sublicensees (including Sublicensees), research collaborators, and financial, legal, and other professional advisors, and in the case of UGARF, to Trust, Anacor, UGA, and Inventor, who reasonably have a need to know such Confidential Information in furtherance of the material purpose of this Agreement ("Third-Party Recipients"), but only after the Third-Party Recipient has signed a written agreement of confidentiality with the Recipient that limits disclosure of, protects, and requires return or destruction of, the Provider's Confidential Information to the same or a greater extent as the terms of this Agreement and the Anacor License Agreement (as applicable). The Recipient disclosing a Provider's Confidential Information to a Third-Party Recipient shall be fully responsible to the Provider for the Third-Party Recipient's full compliance with the terms of this Article 8.

8.4 **Certain Confidential Information Excluded.** A Recipient or Third-Party Recipient shall have no obligations of non-disclosure per Section 8.2 and/or 8.3 with respect to any portion of the Provider's Confidential Information that:

a. is or was already known to the Recipient or Third-Party Recipient at the time of disclosure under this Agreement, as shown by the Recipient's or Third-Party Recipient's written records, without any obligation to keep it confidential;

b. is independently developed by employees of the Recipient or Third-Party Recipient who have not had access to the Confidential Information of the Provider; and/or

c. at the time being disclosed or obtained by the Recipient or Third-Party Recipient under this Agreement or at any time thereafter is published or otherwise generally available to the public other than due to default by the Recipient or Third-Party Recipient of its obligations of confidentiality.

Notwithstanding anything to the contrary herein, each Party shall have the right to disclose Confidential Information of the other Party to the extent required to be disclosed by a competent Court or regulatory authority or otherwise by applicable law, provided that where Licensee is the Recipient and is free to do so, Licensee shall give notice of such disclosure to UGARF as soon as reasonably practicable and assist

UGARF in challenging the order or obtaining confidential treatment of such information. Where such disclosure of information is required under the Freedom of Information Act 2000 and such information relates to Trust, Licensee shall notify UGARF within **[***]** of receiving an information that such request has been made and the details thereof. Licensee shall not make any disclosure during a period of **[***]** and shall on request provide an update of the status of any response regarding information the Licensee has disclosed or intends to disclose.

8.5 **Acknowledgement of Additional Provisions of Anacor License Agreement.** Licensee acknowledges it is informed of the provisions of Articles 12 (Publications), 13 (Announcements), and 14 (Confidentiality) of the Anacor License Agreement.

8.6 **Use of UGARF Names**. None of Licensee and/or any Sublicensee or Contractor shall use the names or marks of UGARF, the University of Georgia, or any of their employees or students in any marketing, advertising, publicity, or other commercial or promotional use without the prior written consent of the owner of the name or mark. Notwithstanding the foregoing, Licensee may use the names of UGARF and the University of Georgia in a true, accurate, and non-misleading fashion in (i) business plans, offering memoranda, and other similar documents for the purpose of raising financing for the operations of Licensee as related to the Licensed Patents and Licensed Products; (ii) as required in Sublicenses and Production Rights Agreements to incorporate UGARF's required interests and terms; and (iii) in any securities reports required to be filed with the Securities and Exchange Commission or similar foreign agency.

8.7 **Use of Trust, Anacor Names.** Licensee shall not use, and Licensee shall require that its Affiliates, Sublicensees, Contractors, and agents shall not use, the registered or unregistered trademarks, service marks, trade dress, trade names, logos, insignia, domain names, symbols, or designs of Anacor, Trust, or any of their respective Affiliates in any press release, publication, or other form of promotional disclosure without the prior written consent of the owner of such, in each instance.

8.8 **Press Releases.** Licensee shall not, and Licensee shall require that its Affiliates, Sublicensees, Contractors, and agents shall not, issue or authorize any press release or other public statement whether written, electronic, oral, or otherwise, disclosing the existence of the Anacor License Agreement or this Agreement, or any Sublicense or Production Rights Agreement at any tier, the terms of any such agreements, or any confidential information relating to any such agreements without the prior written consent of UGARF, Anacor, and Trust, such consent not to be unreasonably withheld or delayed. Notwithstanding the foregoing, no party shall not be prevented from complying with any duty of disclosure it may have pursuant to applicable law or the rules of any recognized stock exchange so long as the disclosing party provides UGARF, Anacor, and Trust at least **[***]** prior written notice to the extent practicable and only discloses information to the extent required by applicable law or the rules of any recognized stock exchange.

ARTICLE 9REPRESENTATIONS AND WARRANTIES; DISCLAIMERS; COVENANTS; LIABILITY; INDEMNITY; AND INSURANCE

9.1 Representations and Warranties.

(a) **Mutual Representations and Warranties.** UGARF and Licensee each represent and warrant to the other that:

i. it has the right, power, and authority to enter into and perform its obligations under this Agreement;

ii. it has full corporate power and authority and has taken all actions necessary to authorize the execution and delivery of this Agreement and the transactions contemplated by this Agreement;

iii. This Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms and applicable law;
iv. All consents, approvals, authorizations, and notifications from or to all governmental authorities and third-parties required by a Party in connection with the Agreement have been obtained or provided; and
v. The execution, delivery, and performance of this Agreement hereby do not and shall not (A) conflict with or result in any breach of any documents or governmental requirements, (B) result in a breach of any agreement to which it is a party or (C) violate any applicable law, rule, or regulation.

(b) **UGARF Representations and Warranties.** UGARF further represents and warrants that:
i. it has the full right, power and authority to grant the rights under the Anacor License Agreement granted pursuant to this Agreement;
ii. it has provided as Schedule 1.1 a full and complete copy of the Anacor License Agreement as currently in effect; and
iii. no consents or notifications are required under the Anacor License Agreement except as shall have been obtained and given prior to the Effective Date.

9.2 **DISCLAIMER OF WARRANTIES**. EXCEPT AS SET OUT IN SECTION 9.1, LICENSED PATENTS ARE PROVIDED "AS IS." UGARF MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, REGARDING ANY LICENSED PATENTS AND/OR LICENSED PRODUCTS, AND UGARF EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE RELATED THERETO OR THAT SUCH DO NOT INFRINGE THIRD-PARTY RIGHTS. NOTHING CONTAINED IN THIS AGREEMENT SHALL BE CONSTRUED AS EITHER A WARRANTY OR REPRESENTATION BY UGARF AS TO THE VALIDITY OR SCOPE OF ANY LICENSED PATENT OR THAT ANY PATENT OR OTHER INTELLECTUAL PROPERTY WILL ISSUE AMONG LICENSED PATENTS.

9.3 **Covenants.** The parties make covenants as follows.

9.3.1 UGARF Covenants. UGARF covenants to Licensee that UGARF shall at all times (a) use its reasonable efforts to maintain the Anacor License Agreement in full force and effect, (b) not amend or otherwise modify the Anacor License Agreement in a manner that would negatively affect the rights and interests of Licensee as set forth in this Agreement without the prior written consent of Licensee, (c) notify Licensee if any Project Compound Intellectual Property (each as defined under the Anacor License Agreement) sublicensed pursuant to this Agreement lapses or otherwise becomes part of the public domain, (d) timely make any and all payments due by UGARF to Anacor or any third-party under the Anacor License Agreement, and (e) notify and provide to Licensee a copy of any amendment or modification of the Anacor License Agreement.

9.3.2 Licensee Covenants. Licensee covenants that Licensee and its Affiliates, Sublicensees, and Contractors shall not enforce any rights in Licensed Patents that may cover Non-Project Compounds (as defined in the Anacor License Agreement) against Anacor, its Affiliates, collaborators, and licensees who practice such Licensed Patents in making, using, or selling Non-Project Compounds (as defined in the Anacor License Agreement).

9.4 **LIMITATION OF LIABILITY.** EACH OF LICENSEE AND UGARF ASSUMES NO LIABILITY, AND SHALL HAVE NO LIABILITY TO LICENSEE OR TO ANY SUBLICENSEE OR CONTRACTOR WHATSOEVER, FOR ANY DIRECT, INDIRECT, SPECIAL, PUNITIVE, INCIDENTAL, LOST PROFITS, AND/OR CONSEQUENTIAL DAMAGES OF ANY KIND (collectively, "DAMAGES") ARISING OUT OF OR RELATED TO LICENSEE'S AND/OR ANY SUBLICENSEE'S OR CONTRACTOR'S PRACTICE OF LICENSED PATENTS AND/OR USE, DEVELOPMENT, OFFER FOR SALE, AND/OR SALE OF LICENSED PRODUCTS, OR WITH RESPECT TO LICENSEE'S AND/OR ANY SUBLICENSEE'S OR CONTRACTOR'S PERFORMANCE UNDER THIS AGREEMENT OR COMMERCIALIZATION OF LICENSED PRODUCTS. LICENSEE AND EACH SUBLICENSEE AND CONTRACTOR EACH ASSUME ALL RISK AND LIABILITIES ASSOCIATED WITH ITS USE OF UGARF CONFIDENTIAL

INFORMATION, LICENSED PATENTS, AND/OR LICENED PRODUCTS, INCLUDING BUT NOT LIMITED THOSE RISKS AND LIABILITIES ARISING OUT OF OR RELATED TO THE SAFETY, UTILITY, VALUE, AND/OR MARKETABILITY OF LICENSED PATENTS AND/OR LICENSED PRODUCTS. THESE LIMITATIONS OF LIABILITY IN SECTION 9.4 APPLY EVEN THOUGH A PARTY OR ANY ONE OR MORE INDEMNIFIED PARTIES, INCLUDING INDEMNITEES (as defined in Section 9.5 below), MAY HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH LIABILITY AND/OR RELATED DAMAGES.

9.5 **INDEMNIFICATION.** LICENSEE SHALL INDEMNIFY, HOLD HARMLESS, AND PAY FOR THE DEFENSE OF UGARF, REGENTS, INVENTOR, AND ALL OF THEIR RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, FACULTY, STUDENTS, EMPLOYEES, CONSULTANTS, AND AGENTS (all collectively "UGARF INDEMNITEES") FROM AND AGAINST ANY AND ALL CLAIMS, LIABILITIES, AND DAMAGES OF ANY KIND ASSERTED AGAINST ANY ONE OR MORE UGARF INDEMNITEES BY ANY THIRD-PARTY INDIVIDUAL OR ENTITY ARISING OUT OF OR RELATED TO LICENSEE'S OR ANY SUBLICENSEE'S OR CONTRACTOR'S PRACTICE OF LICENSED PATENTS, DEVELOPMENT, OFFER FOR SALE, AND/OR SALE OF LICENSED PRODUCTS OR LICENSEE'S AND/OR ANY SUBLICENSEE'S PREFORMANCE UNDER THIS AGREEMENT OR ANY SUBLICENSE, INCLUDING BUT NOT LIMITED TO CLAIMS AGAINST ANY ONE OR MORE UGARF INDEMNITEES MADE BY A PURCHASER OF LICENSED PRODUCT OR ANACOR FOR BREACH OF THE ANACOR LICENSE AGREEMENT CAUSED IN WHOLE OR IN PARTY BY LICENSEE'S CONDUCT OR FAILURE TO ACT. HOWEVER, LICENSEE SHALL HAVE NO OBLIGATION TO A PARTICULAR UGARF INDEMNITEE UNDER THIS SECTION 9.5 WITH RESPECT TO THAT PORTION OF ANY CLAIMS, LIABILITIES, AND/OR DAMAGES DIRECTLY ARISING OUT OF OR RELATED TO THE NEGLIGENCE OR INTENTIONAL MISCONDUCT, OR BREACH OF THIS AGREEMENT, OF SUCH UGARF INDEMNITEE.

9.5.1 Anacor Indemnification. Without limiting the breadth of the foregoing and in addition to the foregoing, Licensee shall indemnify and hold harmless and its Affiliates, and their respective officers, directors, employees, contractors, agents, and assigns (collectively, "Anacor Indemnitees") from and against any and all demands, claims, actions, and proceedings (whether criminal or civil, in contract, tort, or otherwise) for losses, damages, liabilities, costs, and expenses ("Claims") arising or resulting from: (a) Development of a Product by Licensee, it Affiliates, subcontractors, or sublicensees, (b) the Commercialization of a Product by Licensee, its Affiliates, subcontractors, or sublicensees, (c) the negligence, willful misconduct, recklessness or wrongful intentional acts or omissions of Licensee, its Affiliates, subcontractors, or sublicensees, (d) breach by Licensee of any representation, warranty, or covenant as set forth in the Anacor License Agreement or this Agreement, (e) Licensee's use, handling, storage of Licensed Know-How, or (f) Licensee's use, handling, or storage of Licensed Materials; provided that Licensee shall not be obligated to indemnify any Anacor Indemnitees for any Claims made by Anacor. For the purpose of this Section 9.5.1., all capitalized terms not defined in this Agreement shall have the meaning given to them by the Anacor License Agreement.

9.5.2 Anacor Indemnification Procedure. In connection with any Claim for which Anacor seeks indemnification from Licensee pursuant to Section 9.5.1 above, Anacor shall: (a) give UGARF prompt written notice of the Claim; provided, however, that failure to provide such notice shall not relieve the Licensee from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with Licensee, at Licensee's expense, in connection with the defense and settlement of the Claim; and (c) permit UGARF or Licensee, as appropriate, to control the defense and settlement of the Claim; provided, however, that neither UGARF nor Licensee may settle the Claim without Anacor's prior written consent, which shall not be unreasonably withheld or delayed, in the event that such settlement materially adversely impacts Anacor's rights and obligations. Further, Anacor shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of Anacor's selection and at Anacor's own expense. For the purpose of this Section 9.5.2, all capitalized terms not defined in this Agreement shall have the meaning given to them by the Anacor License Agreement.

9.6 **Insurance.** Licensee shall maintain during the term of this Agreement, and Licensee shall require and ensure that each Sublicensee and Contractor shall maintain during the term of their respective Sublicenses or Production Rights Agreement and until the later of: (a) **[***]** after termination or expiration of this Agreement (or the Sublicense or Production Rights Agreement, as applicable) or (b) the date that all statutes of limitations covering claims or suits that may be instituted for personal injury based on the sale or use of Licensed Products have expired, commercial general liability insurance from a minimum "A-" AM Best rated insurance company, including prior to the date of first use of a License Product in humans, contractual liability and product liability or clinical trials, if applicable, with coverage limits of not less than **[***]** per occurrence and **[***]** in the aggregate. Total limits may be provided by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on Licensee's or any third-party's liability hereunder. All such policies shall name UGARF, Regents, UGA, Anacor, and Anacor Affiliates as additional insured (usually for U.S., Canada, and Puerto Rico exposures) or indemnify UGARF, Regents, UGA, Anacor, and Anacor Affiliates as principal (usually for rest of world exposures) and provide a waiver of subrogation in favor of UGARF, Regents, UGA, Anacor, and Anacor Affiliates. Such insurance policies shall be primary and non-contributing with respect to any other similar insurance policies available to Anacor or its Affiliates, or to UGARF, Regents, or UGA. Any deductibles for such insurance shall be assumed by Licensee (or by the Sublicensee or Contractor, as applicable). Upon receipt by the Licensee (or Sublicensee or Contractor, as applicable), Licensee shall provide UGARF and Anacor with certified copies of the insurance policies required under this Section 9.6 or original certificates of insurance evidencing such insurance prior to first use of a Project Compound (as defined by the Anacor License Agreement) or Licensed Product in humans. Licensee shall provide notification, and subsequently notify UGARF and Anacor at least thirty days prior to cancellation, termination, or any material change to restrict coverage or reduce limits afforded in any such insurance policies.

ARTICLE 10TERM AND TERMINATION

10.1 **Term.** Unless sooner removed or terminated by this terms of this Agreement or the mutual consent of the Parties, the rights granted to Licensee by this Agreement in each Licensed Patent and sublicensed to Licensee under the Anacor License Agreement shall survive and extend through and including the last day there remains in effect at least one Valid Claim of such Licensed Patent, at which time it is no longer included among Licensed Patents or sublicensed under the Anacor License Agreement.

10.2 **Termination by Licensee.** Licensee may terminate this Agreement by delivering notice of termination to UGARF, and in that event the effective date of termination will be the later of either (a) 30 days from the date of receipt of the notice of termination; or (b) a later termination date identified in the notice.

10.3 **Termination by UGARF**. If Licensee or a Sublicensee or Contractor materially breaches any term of this Agreement and fails to cure such breach within 60 days after Licensee's receipt of written notice of such breach by UGARF, then UGARF may thereafter deliver, at any time during the term of this Agreement while the noticed breach remains uncured, a notice of termination to Licensee, in which case all of Licensee's rights under this Agreement automatically shall terminate as of the date of Licensee's receipt of such notice of termination or on a later termination date identified in the notice. Notwithstanding the foregoing, if Licensee files any action that challenges UGARF's rights in any one or more Licensed Patents, then UGARF may send notice of termination to Licensee, in which case termination is effective immediately upon Licensee's receipt of such notice.

10.4 **Effect of Termination on Licensed Patent Rights.** Upon termination or removal from the scope of this Agreement of Licensee's rights in and to any particular Licensed Patent prior to its natural termination, then Licensee and all Sublicensees and Contractors shall immediately cease practicing such Licensed Patent and, without limiting the foregoing, they all shall immediately cease making use of such Licensed Patent rights to make, have made, offer to sell, and/or sell any Licensed Products.

10.5 **Effects of Termination on Confidential Information.** Once all rights in Licensed Patents granted to Licensee hereunder have either expired, been removed from the scope of this Agreement, or have otherwise terminated, then each Recipient and Third-Party Recipient of the Provider's Confidential Information shall destroy all such Confidential Information in such Recipient's and/or Third-Party Recipient's possession or control; or upon timely notice from the Provider, the Recipient and each Third-Party Recipient shall return such Confidential Information to the Provider at the Provider's expense. However, each Recipient and Third-Party Recipient may keep archival copies of the Provider's Confidential Information to the extent required by applicable records retention policies, law, or regulation, but with the requirement that except to the extent required by law the Recipient and/or Third-Party Recipient may not use or access any such retained Confidential Information of the Provider for any purpose whatsoever unless or until such retained Confidential Information meets one of the exceptions at Sections 8.5(a)-(e).

10.6 **Survival.** Notwithstanding termination or expiration of this Agreement for any reason, the following provisions shall survive:

(a). Licensee's payment obligations that are accrued and remaining unpaid or unperformed prior to such termination;
(b). Licensee's reporting obligations that are accrued but remaining unmet or unperformed prior to termination;
(c). Sections 2.3.3, 2.3.4 2.3.5,2.3,6, 4.8, 4.9, 4.10, 4.11, 4.12, 5.4, 5.5, and 6.8 and Articles 7, 8, 9, 10, and 11;
(d). Any cause of action or claim of a party, accrued or to accrue, as a result of any breach or default of this Agreement or performance of this Agreement.

ARTICLE 11MISCELLANEOUS

11.1 **Integration**. This Agreement, including its Appendices, contains the entire understanding of the Parties with respect to the subject matter of this Agreement and supersedes any and all prior written or oral discussions, arrangements, courses of conduct, or agreements with respect to the same subject matter; provided that any contemporaneous agreements executed by the Parties for research or other funding shall be read independently of this Agreement.

11.2 **Amendment and Waiver.** Except as expressly permitted herein, this Agreement may be amended only by a written instrument executed by both Parties. The waiver of an obligation hereunder by a Party shall not constitute a waiver of any other obligation, and shall not constitute a permanent waiver of that obligation.

11.3 **Assignment.** This Agreement shall not be assigned by Licensee without the prior written consent of UGARF at UGARF's sole discretion, except that no consent shall be required in the case of assignment or transfer to a party that succeeds to all or substantially all of Licensee's business or assets relating to this Agreement, whether by sale, merger, operation of law, or otherwise, provided that such assignee or transferee promptly agrees to be bound by the terms and conditions of this Agreement. Any purported assignment not in accordance with this Section 11.3 is void. Licensee shall provide UGARF with a copy of assignment within 5 days of execution.

11.4 **Severability**. If any one or more of the provisions of this Agreement is held by any court of competent jurisdiction to be invalid, illegal, or unenforceable, then such provisions shall be reformed to approximate as nearly as possible the intent of the Parties, and the validity of the remaining provisions shall not be affected. If it is not possible to reform the Agreement while maintaining the material intent of the Parties, then this Agreement shall automatically terminate.

11.5 **Relationship of Parties.** The Parties are independent contractors. There is no relationship of principal to agent, master to servant, employer to employee, or franchiser to franchisee between the Parties. Neither Party has the authority to bind the other or incur any obligation on its behalf except as may be expressly provided herein.

11.6 **Governing Law; Jurisdiction**. This Agreement is governed and interpreted under the laws of the State of Georgia applicable to contracts made and to be performed entirely within Georgia by Georgia residents without regard to the conflicts of laws rules of any jurisdiction. All actions or proceedings related to this Agreement shall be litigated in the U.S. District Court for the Middle District of Georgia.

11.7 **Export Controls**. Licensee acknowledges that the practice of Licensed Patents, and/or the development, manufacture, transport, and/or sale of Licensed Products, may require a license or other prior permission or approval from an agency or other unit of the U.S. government, and that certain financial transactions with foreign individuals or entities may be barred. UGARF neither represents that any such license or other prior permission or approval will not be required nor that, if required, such shall issue. Licensee shall comply, and Licensee shall ensure that its Sublicensees and Contractors shall comply, with any and all such requirements acknowledged herein.

11.8 **Force Majeure.** Delays in, or failure of, performance by any Party will not constitute default, or trigger any claim for damages, if and to the extent such damages are caused by acts of God, strikes, work stoppages, civil disturbances, fires, floods, explosions, riots, war, rebellion, and/or sabotage.

11.9 **Notices**. Notices required under this Agreement shall be delivered to a Party at its address set forth below. Notice may be given by hand or by commercial carrier, or by email where indicated. Such notice is effective upon receipt by an employee, agent, or representative of the receiving Party authorized to receive notices or other communications sent or delivered in a manner set forth above.

If to UGARF: Director, Innovation Gateway
University of Georgia Research Foundation, Inc.
110 Terrell Hall
210 S. Jackson Street
Athens, Georgia 30602

If to Licensee: Chief Legal Officer
AN2 Therapeutics, Inc.
1800 El Camino Real, Suite D
Menlo Park, CA 94027
[***]
[***]

11.10 **Implementation**. Each Party shall, at the request of the other Party, execute any documents reasonably necessary to implement the provisions of this Agreement.

11.11 **Remedies.** Due to the proprietary nature of the subject matter, the Parties agree that their respective rights and obligations under this Agreement may be enforced by injunction, specific performance, or other equitable relief, without prejudice to any other rights and remedies the Parties may have at law or equity.

11.12 **Not Binding until Executed and Delivered.** Unless and until all Parties hereto have executed and delivered this Agreement, this Agreement shall be of no force or effect.

11.13 **Third-Party Beneficiary.** Anacor is a third-party beneficiary of this Agreement with the right to enforce Licensee's obligations to Anacor herein, including but not limited to those obligations to Anacor in Section 2.5. (Anacor Retained Rights); Sections 9.5.1. and 9.5.2. (Indemnification); Section 11.6.1 (Use of Names); Section11.6.2 (Press Release); and Section 9.6 (Insurance). Licensee shall also require that Anacor be included as a third-party beneficiary of any Sublicense or Production Rights Contract with the right to enforce such Sublicensee's or Contractor's obligations to Anacor that are required by this Agreement, including but not limited those obligations to Anacor identified above.

IN WITNESS WHEREOF, the Parties hereto have caused this License Agreement to be executed by their authorized officers or representatives on the date indicated below.

University of Georgia Research Foundation, Inc.		**AN2 Therapeutics, Inc.**	
By:	/s/ Derek E. Eberhart	By:	
Name:	Dr. Derek E. Eberhart	Name:	Eric Easom
Title:	Chief Licensing Officer	Title:	President & CEO
Date:		Date:	

APPENDIX A
[***]

APPENDIX B
[***]

APPENDIX C
[***]

APPENDIX D
[***]

APPENDIX D-1
[***]

APPENDIX E
[***]

SCHEDULE 1.1
Copy of Anacor License Agreement

Exhibit 19.1

AN2 THERAPEUTICS, INC.
INSIDER TRADING POLICY

Approved by the Board of Directors: February 18, 2022
Effective: March 24, 2022

INTRODUCTION

During the course of your relationship with AN2 Therapeutics, Inc. ("***AN2***"), you may receive material information that is not yet publicly available ("***material nonpublic information***") about AN2 or other publicly traded companies that AN2 has business relationships with. Material nonpublic information may give you, or someone you pass that information on to, a leg up over others when deciding whether to buy, sell or otherwise transact in AN2's securities or the securities of another publicly traded company. This policy sets forth guidelines with respect to transactions in AN2 securities and in the securities of other applicable publicly traded companies, in each case by our employees, directors and consultants who may become aware of material non-public information and the other persons subject to this policy as described below.

STATEMENT OF POLICY

It is the policy of AN2 that an employee, director or consultant of AN2 (or any other person subject to this policy) who is aware of material nonpublic information relating to AN2 **may not**, directly or indirectly:

1. engage in any transactions in AN2's securities, except as otherwise specified under the heading "Exceptions to this Policy" below;
2. recommend the purchase or sale of any AN2's securities;
3. disclose material nonpublic information to persons within AN2 whose jobs do not require them to have that information, or outside of AN2 to other persons, such as family, friends, business associates and investors, unless the disclosure is made in accordance with AN2's policies regarding the protection or authorized external disclosure of information regarding AN2; or
4. assist anyone engaged in the above activities.

The prohibition against insider trading is absolute. It applies ***even if*** the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of **any** material nonpublic information relating to AN2 at the time of the transaction.

The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve AN2's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

It is also important to note that the laws prohibiting insider trading are not limited to trading by the insider alone; advising others to trade on the basis of material nonpublic information is illegal and squarely prohibited by this policy. Liability in such cases can extend both to the "tippee"—the person to whom the insider disclosed material nonpublic information—and to the "tipper," the insider himself or herself. In such cases, you can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. For these and other reasons, it is the policy of AN2 that no employee, director or consultant of AN2 (or any other person subject to this policy) may either (a) recommend to

another person that they buy, hold or sell AN2's securities **at any time** or (b) disclose material nonpublic information to persons within AN2 whose jobs do not require them to have that information, or outside of AN2 to other persons (unless the disclosure is made in accordance with AN2's policies regarding the protection or authorized external disclosure of information regarding AN2).

In addition, it is the policy of AN2 that no person subject to this policy who, in the course of his or her relationship with AN2, learns of any confidential information that is material to another publicly traded company, including but not limited to a customer, supplier, partner or collaborator of AN2 or an economically-linked company such as a competitor of AN2, may trade in that other company's securities until the information becomes public or is no longer material to that other company.

There are no exceptions to this policy, except as specifically noted above or below.

Transactions Subject to this Policy

This policy applies to all transactions in securities issued by AN2, as well as derivative securities that are not issued by AN2, such as exchange-traded put or call options or swaps relating to AN2's securities. Accordingly, for purposes of this policy, the terms "***trade***," "***trading***" and "***transactions***" include not only purchases and sales of AN2's common stock in the public market but also any other purchases, sales, transfers or other acquisitions and dispositions of common or preferred equity, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

Persons Subject to this Policy

This policy applies to you and all other employees, directors and consultants of AN2 and its subsidiaries. This policy also applies to members of your immediate family, persons with whom you share a household, persons who are your economic dependents and any other individuals or entities whose transactions in securities you influence, direct or control (including, e.g., a venture or other investment fund, if you influence, direct or control transactions by the fund). The foregoing persons who are deemed subject to this policy are referred to in this policy as "***Related Persons***." You are responsible for making sure that your Related Persons comply with this policy.

Material Nonpublic Information

Material information

It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor to determine whether nonpublic information you know about a public company is material: whether the information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities. If the information makes you want to trade, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material.

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed within the meaning of this policy. There may be other types of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

- financial results or forecasts;
- status of product or product candidate development or regulatory approvals;
- clinical or pre-clinical data relating to products or product candidates;
- timelines for pre-clinical studies or clinical trials;
- acquisitions or dispositions of assets, divisions or companies;

- public or private sales of debt or equity securities;
- stock splits, dividends or changes in dividend policy;
- the establishment of a repurchase program for AN2's securities;
- gain or loss of a significant licensor, licensee or supplier; and
- changes or new corporate partner relationships or collaborations.
- notice of issuance or denial of patents;
- regulatory developments;
- management or control changes;
- employee layoffs;
- a disruption in AN2's operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;
- tender offers or proxy fights;
- accounting restatements;
- litigation or settlements; and
- impending bankruptcy.

When information is considered public

The prohibition on trading when you have material nonpublic information lifts once that information becomes publicly disseminated. But for information to be considered publicly disseminated, it must be widely disseminated through a press release, a filing with the Securities and Exchange Commission (the "***SEC***"), or other widely disseminated announcement. Once information is publicly disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy only after two full trading days have elapsed since the information was publicly disclosed. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. Depending on the particular circumstances, AN2 may determine that a longer or shorter waiting period should apply to the release of specific material nonpublic information.

Blackout Periods

Generally, except as set forth in this policy, AN2 directors, employees and designated consultants may buy or sell securities of the Company at any time other than during a blackout period (as defined below). From time to time, the Chief Executive Officer or Chief Legal Officer may require that directors, employees and designated consultants suspend trading in the Company's securities because there exists undisclosed information that would make trades by them inappropriate. The period during which trading is suspended is referred to in this policy as a "***blackout period***." In that situation, AN2 will notify the designated individuals that neither they nor their Related Persons may trade in the AN2's securities. It is important to note that the fact that the Company is in a blackout period should be considered material nonpublic information that should not be communicated to any other person. Even if you have not been designated as a person who should not trade due to an event-specific trading blackout, you should not trade while aware of material nonpublic information.

An AN2 employee, director or consultant who believes that special circumstances require him or her to trade during a blackout period should consult the Chief Legal Officer. Permission to trade during a blackout period will be granted only where the circumstances are extenuating, the Chief Legal Officer concludes that the person is not in fact aware of any material nonpublic information relating to AN2 or its securities, and there appears to be no significant risk that the trade may subsequently be questioned.

The blackout period restrictions do not apply to those transactions to which this policy does not apply, as described under the heading "Exceptions to this Policy" below.

Exceptions to this Policy

This policy does not apply in the case of the following transactions, except as specifically noted:

1.*Option Exercises*. This policy does not apply to the exercise of options granted under AN2's equity compensation plans for cash or, where permitted under the option, by a net exercise transaction with the Company. This policy does, however, apply to any sale of stock as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

2.*Tax Withholding Transactions*. This policy does not apply to the surrender of shares directly to AN2 to satisfy tax withholding obligations as a result of the issuance of shares upon vesting or exercise of restricted stock units, options or other equity awards granted under AN2's equity compensation plans. Of course, any market sale of the stock received upon exercise or vesting of any such equity awards remains subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

3.*ESPP*. This policy does not apply to the purchase of stock by employees under AN2's Employee Stock Purchase Plan ("***ESPP***") on periodic designated dates in accordance with the ESPP. This policy does, however, apply to any sale of stock acquired pursuant to the ESPP.[1]

4.*10b5-1 Automatic Trading Programs*. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), and as permitted by AN2, employees, directors and consultants may establish a trading plan under which a broker is instructed to buy and sell AN2 securities based on pre-determined criteria (a "***Trading Plan***"). So long as a Trading Plan is properly established, purchases and sales of AN2 securities pursuant to that Trading Plan are not subject to this policy. To be properly established, an eligible person's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable 10b5-1 trading plan guidelines of AN2 at a time when they were unaware of any material nonpublic information relating AN2 and when AN2 was not otherwise in a trading blackout period. Moreover, all Trading Plans must be reviewed and approved by AN2 before being established to confirm that the Trading Plan complies with all pertinent company policies and applicable securities laws.

5.*Gifts.* This policy does not apply to *bona fide* gifts of AN2 securities that have been pre-cleared by AN2's Chief Legal Officer or his or her designee. Whether a gift is truly *bona fide* will depend on the facts and circumstances surrounding each gift. Pre-clearance must be obtained at least two business days in advance of the proposed gift, and pre-cleared gifts not completed within five business days will require new pre-clearance. AN2 may choose to shorten this period.

SPECIAL AND PROHIBITED TRANSACTIONS

1.***Inherently Speculative Transactions.*** No AN2 employee, director or consultant may engage in short sales, transactions in put options, call options or other derivative securities on an exchange or in any other organized market, or in any other inherently speculative transactions with respect to AN2's stock.

2.***Hedging Transactions.*** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit an AN2 employee, director or consultant to continue to own AN2's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the AN2 employee, director or consultant may no longer have the same objectives as AN2's other stockholders.

---

[1] If an ESPP election or change is in any manner tied to a market transaction, the optional language below should replace the final sentence:
"This policy does however apply to an employee's initial election to participate in the ESPP, changes to an employee's election to participate in the ESPP for any enrollment period, or to the subsequent sale of the stock acquired pursuant to the ESPP."

Therefore, AN2 employees, directors and consultants are prohibited from engaging in any such transactions.][2]

3.***Margin Accounts and Pledged Securities***. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in AN2's securities, AN2 employee, director and consultants are prohibited from holding AN2's securities in a margin account or otherwise pledging AN2's securities as collateral for a loan.

4.***Standing and Limit Orders***. Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when an AN2 employee, director or consultant is in possession of material nonpublic information. AN2 therefore discourages placing standing or limit orders on AN2's securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Blackout Periods" provision above.

PRE-CLEARANCE AND ADVANCE NOTICE OF TRANSACTIONS

In addition to the requirements above, officers, directors and other applicable members of management who have been notified that they are subject to pre-clearance requirements face a further restriction: They may not engage in any transaction in AN2's securities without first obtaining pre-clearance of the transaction from AN2's Chief Legal Officer or his or her designee at least two business days in advance of the proposed transaction. The Chief Legal Officer or his or her designee will then determine whether the transaction may proceed and, if so, will direct the Compliance Coordinator (as identified in AN2's Section 16 Compliance Program) to help comply with any required reporting requirements under Section 16(a) of the Exchange Act. Pre-cleared transactions not completed within five business days will require new pre-clearance. AN2 may choose to shorten this period.

Persons subject to pre-clearance must also give advance notice of their plans to exercise an outstanding stock option to the Chief Legal Officer. Once any transaction takes place, the officer, director or applicable member of management must immediately notify the Compliance Coordinator and any other individuals identified under the heading "Notification of Execution of Transaction" in AN2's Section 16 Compliance Program so that AN2 may assist in any Section 16 reporting obligations.

SHORT-SWING TRADING, CONTROL STOCK AND SECTION 16 REPORTS

Officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5), which are described in AN2's Section 16 Compliance Program, and any notices of sale required by Rule 144.

POLICY'S DURATION

This policy continues to apply to your transactions in AN2's securities and the securities of other applicable public companies as more specifically set forth in this policy, even after your relationship with AN2 has ended. If you are aware of material nonpublic information when your relationship with AN2 ends, you may not trade AN2's securities or the securities of other applicable publicly traded companies until the material nonpublic information has been publicly disseminated or is no longer material. Further, if you leave AN2 during a trading blackout period, then you may not trade AN2's securities or the securities of other applicable companies until the trading blackout period has ended.

INDIVIDUAL RESPONSIBILITY

Persons subject to this policy have ethical and legal obligations to maintain the confidentiality of information about AN2 and to not engage in transactions in AN2's securities or the securities of other applicable public companies while aware of material nonpublic information, as more specifically set forth in this policy. Each individual is responsible for making sure that he or she complies with this policy, and that any family member, household member or other person or entity whose transactions are subject to this policy, as discussed under the heading "Persons Subject to this Policy" above, also comply with this policy. In all cases, the responsibility for determining whether an individual is aware of material nonpublic information rests with that individual, and any action on the part of AN2 or any employee or director of AN2 pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by AN2 for any conduct prohibited by this policy or applicable securities laws. See "Penalties" below.

PENALTIES

Anyone who engages in insider trading or otherwise violates this policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by AN2, including termination of employment. Anyone who has questions about this policy should contact their own attorney or AN2's Chief Legal Officer. Please also see Frequently Asked Questions, which are attached as **EXHIBIT A**.

AMENDMENTS

AN2 is committed to continuously reviewing and updating its policies and procedures. AN2 therefore reserves the right to amend, alter or terminate this policy at any time and for any reason. A current copy of the AN2's policies regarding insider trading may be obtained by contacting the Chief Legal Officer.

EXHIBIT A
INSIDER TRADING POLICY
FREQUENTLY ASKED QUESTIONS

1. ***What is insider trading?***

A: Generally speaking, insider trading is the buying or selling of stocks, bonds, futures or other securities by someone who possesses or is otherwise aware of material nonpublic information about the securities or the issuer of the securities. Insider trading also includes trading in derivatives (such as put or call options) where the price is linked to the underlying price of a company's stock. It does not matter whether the decision to buy or sell was influenced by the material nonpublic information, how many shares you buy or sell, or whether it has an effect on the stock price. Bottom line: If, during the course of your relationship with AN2, you become aware of material nonpublic information about AN2 and you trade in AN2's securities, you have broken the law and violated our insider trading policy. In addition, our insider trading policy provides that if in the course of your relationship with AN2, you learn of any confidential information that is material to another publicly traded company, including but not limited to a customer, supplier, partner or collaborator of AN2 or an economically-linked company such as a competitor of AN2, you may not trade in that other company's securities until the information becomes public or is no longer material to that other company. For example, if you learn of nonpublic information during the course of your relationship with AN2 that could affect the stock price of an AN2 competitor, you may not trade in that competitor's stock until the information becomes public or is no longer material.

2. ***Why is insider trading illegal?***

A: If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the market. This ensures that there is an even playing field by requiring those who are aware of material nonpublic information to refrain from trading.

3. ***What is material nonpublic information?***

A: Information is material if it would influence a reasonable investor to buy or sell a stock, bond future or other security. This could mean many things: financial results, clinical or regulatory results, potential acquisitions or major contracts to name just a few. Information is nonpublic if it has not yet been publicly disseminated within the meaning of our insider trading policy.

4. ***Who can be guilty of insider trading?***

A: Anyone who buys or sells a security while aware of material nonpublic information, or provides material nonpublic information that someone else uses to buy or sell a security, may be guilty of insider trading. This applies to all individuals, including officers, directors and others who don't even work at AN2. Regardless of who you are, if you know something material about the value of a security that not everyone knows and you trade (or convince someone else to trade) in that security, you may be found guilty of insider trading.

5. ***Does AN2 have an insider trading policy?***

A: Yes, the insider trading policy is available to read on our website at [●].

6. ***What if I work in a foreign office?***

A: The same rules apply to U.S. and foreign employees and consultants. The Securities and Exchange Commission (the U.S. government agency in charge of investor protection) and the Financial Industry Regulatory Authority (a private regulator that oversees U.S. securities exchanges) routinely investigate trading in a company's securities conducted by individuals and firms based abroad. In addition, as an AN2 director, employee or consultant, our policies apply to you no matter where you work.

7. ***What if I don't buy or sell anything, but I tell someone else material nonpublic information and they buy or sell?***

A: That is called "tipping." You are the "tipper" and the other person is called the "tippee." If the tippee buys or sells based on that material nonpublic information, both you and the "tippee" could be found guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members and the "tippee" might be found guilty of insider trading too. To prevent this, you may not discuss material nonpublic information about the company with anyone outside AN2, including spouses, family members, friends or business associates (unless the disclosure is made in accordance with AN2's policies regarding the protection or authorized external disclosure of information regarding AN2). This includes anonymous discussions on the internet about AN2or companies with which AN2 does business.

8. ***What if I don't tell them the information itself; I just tell them whether they should buy or sell?***

A: That is still tipping, and you can still be responsible for insider trading. You may never recommend to another person that they buy, hold or sell AN2's common stock or any derivative security related to AN2's common stock, since that could be a form of tipping.

9. ***What are the sanctions if I trade on material nonpublic information or tip off someone else?***

A: In addition to disciplinary action by AN2—which may include termination of employment—you may be liable for civil sanctions for trading on material nonpublic information. The sanctions may include return of any profit made or loss avoided as well as penalties of up to three times any profit made or any loss avoided. Persons found liable for tipping material nonpublic information, even if they did not trade themselves, may be liable for the amount of any profit gained or loss avoided by everyone in the chain of tippees as well as a penalty of up to three times that amount. In addition, anyone convicted of criminal insider trading could face prison and additional fines.

10. ***What is "loss avoided"?***

A: If you sell common stock or a related derivative security before negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news.

11. ***Am I restricted from trading securities of any companies other than AN2, for example a partner or competitor of AN2?***

A: Yes, you may be restricted from doing so due to your awareness of material nonpublic information. U.S. insider trading laws generally restrict everyone aware of material nonpublic information about a company from trading in that company's securities, regardless of whether the person is directly connected with that company, except in limited circumstances. You should be particularly conscious of this restriction if, through your position at AN2, you sometimes obtain sensitive, material information about other companies and their business dealings with AN2. Please also refer to Question 1 above and our insider trading policy with respect to restrictions on trading in the securities of other public companies.

12. ***So if I do not trade AN2 securities when I have material nonpublic information, and I don't "tip" other people, I am in the clear, right?***

A: Not necessarily. Even if you do not violate U.S. law, you may still violate our policies. For example, employees and consultants may violate our policies by breaching their confidentiality obligations or by recommending AN2 stock as an investment, even if these actions do not violate securities laws. Our policies are stricter than the law requires so that we and our employees and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.

13. ***So when can I buy or sell my AN2 securities?***

A: If you are aware of material nonpublic information, you may not buy or sell our common stock until two full trading days have elapsed since the information was publicly disclosed. At that point, the information is considered publicly disseminated for purposes of our insider trading policy. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. **Even if you are not aware of any material nonpublic information, you may not trade our common stock during any trading "blackout" period**. Our insider trading policy describes the blackout periods, which may be announced by email.

14. ***If I have an open order to buy or sell AN2 securities on the date a blackout period commences, can I leave it to my broker to cancel the open order and avoid executing the trade?***

A: No, unless it is in connection with a 10b5-1 trading plan (see Question 27 below). If you have any open orders when a blackout period commences other than in connection with a 10b5-1 trading plan, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after a blackout period commences not in connection with a 10b5-1 trading plan, you will have violated our insider trading policy and may also have violated insider trading laws.

15. ***Am I allowed to trade derivative securities of AN2's common stock?***

A: No. Under our policies, you may not trade in derivative securities related to our common stock, which include publicly traded call and put options. In addition, under our policies, you may not engage in short selling of our common stock at any time.

"Derivative securities" are securities other than common stock that are speculative in nature because they permit a person to leverage their investment using a relatively small amount of money. Examples of derivative securities include "put options" and "call options." These are different from employee options and other equity awards granted under our equity compensation plans, which are not derivative securities for purposes of our policy.

"Short selling" is profiting when you expect the price of the stock to decline, and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is realized if the stock price decreases during the period of borrowing.

16. ***Why does AN2 prohibit trading in derivative securities and short selling?***

A: Many companies with volatile stock prices have adopted similar policies because of the temptation it represents to try to benefit from a relatively low-cost method of trading on short-term swings in stock prices, without actually holding the underlying common stock, and encourages speculative trading. We are dedicated to building stockholder value, short selling our common stock conflicts with our values and would not be well-received by our stockholders.

17. ***Can I purchase AN2 securities on margin or hold them in a margin account?***

A: Under our policies, you may not purchase our common stock on margin or hold it in a margin account at any time.

"Purchasing on margin" is the use of borrowed money from a brokerage firm to purchase our securities. Holding our securities in a margin account includes holding the securities in an account in which the shares can be sold to pay a loan to the brokerage firm.

18. ***Why does AN2 prohibit me from purchasing AN2 securities on margin or holding them in a margin account?***

A: Margin loans are subject to a margin call whether or not you possess material nonpublic information at the time of the call. If a margin call were to be made at a time when you were aware of material nonpublic information and you could not or did not supply other collateral, you may be liable under insider trading laws because of the sale of the securities (through the margin call). The sale would be attributed to you even though the lender made the ultimate determination to sell. The U.S. Securities and Exchange Commission takes the view that you made the determination to not supply the additional collateral and you are therefore responsible for the sale.

19. ***Can I pledge my AN2 shares as collateral for a personal loan?***

A: No. Pledging your shares as collateral for a personal loan could cause the pledgee to transfer your shares during a trading blackout period or when you are otherwise aware of material nonpublic information. As a result, you may not pledge your shares as collateral for a loan.

20. ***Can I hedge my ownership position in AN2?***

A: Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds are prohibited by our insider trading policy. Since such hedging transactions allow you to continue to own AN2's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership, you may no longer have the same objectives as AN2's other stockholders. Therefore, our insider trading policy prohibits you from engaging in any such transactions.

21. ***Can I exercise options granted to me under AN2's equity compensation plans during a trading blackout period or when I possess material nonpublic information?***

A: Yes. You may exercise the options for cash (or via net exercise transaction with the company) and receive shares, but you may not sell the shares (even to pay the exercise price or any taxes due) during a trading blackout period or any time that you are aware of material nonpublic information. To be clear, you may not effect a broker-assisted cashless exercise (these cashless exercise transactions include a market sale) during a trading blackout period or any time that you are aware of material nonpublic information

22. ***Am I subject to trading blackout periods if I am no longer an employee or consultant of AN2?***

A: It depends. If your employment with AN2 ends during a trading blackout period, you will be subject to the remainder of that trading blackout period. However, even if you are not subject to our trading blackout period after you leave AN2, you should not trade in AN2 securities if you are aware of material nonpublic information. That restriction stays with you as long as the information you possess is material and not publicly disseminated within the meaning of our insider trading policy.

23. ***Can I gift stock while I possess material nonpublic information or during a trading blackout period?***

A: It depends. Because of the potential for the appearance of impropriety, you may only make *bona fide* gifts of our common stock when you are aware of material nonpublic information or during a trading blackout period if (and only if) the gift has been pre-cleared by AN2's Chief Legal Officer or his or her designee. Whether a gift is truly *bona fide* will depend on the facts and circumstances surrounding each gift.

24. ***What if I purchased publicly traded options or other derivative securities before I became an AN2 employee or consultant?***

A: The same rules apply as for employee stock options. You may exercise the publicly traded options at any time, but you may not sell the securities during a trading blackout period or at any time that you are aware of material nonpublic information.

25. ***May I own shares of a mutual fund that invests in AN2?***

A: Yes.

26. ***Are mutual fund shares holding AN2 common stock subject to the trading blackout periods?***

A: No. You may trade in mutual funds holding AN2 common stock at any time.

27. ***May I use a "routine trading program" or "10b5-1 plan"?***

A: Subject to the requirements discussed in our insider trading policy and any 10b5-1 trading plan guidelines, eligible persons may use a routine trading program. A routine trading program, also known as a 10b5-1 plan, allows you to set up a highly structured program with your stock broker where you specify ahead of time the date, price, and amount of securities to be traded. If you wish to create a 10b5-1 plan, please contact our finance team to confirm you are an eligible person and to obtain approval.

28. ***What happens if I violate our insider trading policy?***

A: Violating our policies may result in disciplinary action, which may include termination of your employment or other relationship with AN2. In addition, you may be subject to criminal and civil sanctions.

29. ***Who should I contact if I have questions about our insider trading policy or specific trades?***

A: You should contact our Chief Legal Officer.

Acknowledgement

I have read and understand the requirements of this policy.

Name:
Date:
Signature:

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-263917, No. 333-270962 and No. 333-278399) and S-3 (No. 333-271174) of AN2 Therapeutics, Inc. of our report dated March 25, 2025 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 25, 2025

Exhibit 31.1

CERTIFICATION 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

I, Eric Easom, certify that:

1. I have reviewed this Annual Report on Form 10-K of AN2 Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

Date: March 25, 2025

By: /s/ Eric Easom
Eric Easom
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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

I, Lucy O. Day, certify that:

1. I have reviewed this Annual Report on Form 10-K of AN2 Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

Date: March 25, 2025

By: /s/ Lucy O. Day
Lucy O. Day
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of AN2 Therapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and

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

Date: March 25, 2025

By: /s/ Eric Easom
Eric Easom
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Annual Report of AN2 Therapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and

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

Date: March 25, 2025

By: /s/ Lucy O. Day
Lucy O. Day
Chief Financial Officer
(Principal Financial Officer)