

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, 2022

OR

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

TO
Commission File Number 001-41331

AN2 Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

1800 El Camino Real, Suite D
Menlo Park, California

(Address of principal executive offices)

82-0606654

(I.R.S. Employer
Identification No.)

94027

(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	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, 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 30, 2022, was \$118,888,897.

The number of shares of Registrant's Common Stock outstanding as of March 22, 2023 was 19,402,658 shares of common stock, par value \$0.00001, outstanding.

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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;
- the ability of our pivotal Phase 2/3 clinical trial in mycobacterium avium complex (“MAC”) lung disease to be sufficient for regulatory approval in the United States and Japan and potentially other territories;
- 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;
- the expected post-approval marketing exclusivity granted to epetraborole by certain regulatory designations 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 the COVID-19 pandemic on our business and operations, including clinical trials, manufacturing suppliers, collaborators, use of contract research organizations (“CROs”) and employees;
- our expectations regarding the impact of inflation, macroeconomic conditions and geopolitical conflicts on our business and operations, including on our manufacturing suppliers, collaborators, 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” and elsewhere in this Annual Report. 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.

RISK FACTORS SUMMARY

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should carefully consider the risks and uncertainties described under “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K as part of your evaluation of an investment in our common stock.

- 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 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 depend to a large degree on the success of epetraborole, for which we have initiated patient enrollment in a pivotal Phase 2/3 clinical trial. If we do not obtain regulatory approval for and successfully commercialize epetraborole or any of our future product candidates, or if we experience significant delays in doing so, we may never become profitable.
- If clinical trials of epetraborole or any future product candidate that we may advance to clinical trials fail to demonstrate safety, tolerability, and/or efficacy to the satisfaction of the U.S. Food and Drug Administration (“FDA”), Japan’s Pharmaceuticals and Medical Devices Agency (“PMDA”), the European Medicines Agency (“EMA”), the Therapeutic Goods Administration in Australia (“TGA”), 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 epetraborole or any future product candidate.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- We rely on single-sourced third parties to conduct the preclinical and nonclinical studies, clinical trials, and manufacture of our clinical trial material for epetraborole and our future product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies, trials, and manufacturing services or failing to comply with applicable regulatory requirements.
- Even if epetraborole or any of our future product candidates receives marketing approval, they 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. If we are unable to establish sales, marketing, and distribution capabilities for epetraborole or our future 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 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. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail 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, epetraborole, and our other future product candidates are subject, in large part, to the terms and conditions of licenses granted to us by others, including 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 epetraborole or our future 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 epetraborole or our future product candidates, and our ability to generate revenue will be materially impaired.
- Future legislation, and/or regulations and policies adopted by the FDA, the PMDA, the EMA, the TGA or comparable regulatory authorities, may increase the time and cost required for us to conduct and complete clinical trials of epetraborole or other future product candidates.
- The trading price of our common stock may be volatile.
- Our cash and cash equivalents may be exposed to failure of our banking institutions.

PART I

Item 1. Business.

Overview

AN2 Therapeutics, Inc. is a Delaware corporation incorporated on February 24, 2017. We launched operations in November 2019. We are a clinical-stage biopharmaceutical company developing treatments for rare, chronic, and serious infectious diseases with high unmet needs. Our initial candidate is epetraborole, which we are studying as a 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.

We are enrolling patients in a pivotal Phase 2/3 clinical trial evaluating epetraborole in treatment-refractory *Mycobacterium avium* complex (“MAC”), the most common form of NTM lung disease. If the data from the Phase 2/3 trial is positive, we plan to file for regulatory and marketing approval initially in the United States and Japan and potentially other territories. We are also planning to develop epetraborole for treatment-naïve MAC lung disease and *M. abscessus* lung disease.

Epetraborole has 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. In 2022, 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 has the potential to become an important component of a multi-drug treatment regimen for patients suffering from NTM lung disease.

We in-licensed the exclusive worldwide development and commercialization rights for epetraborole from Anacor Pharmaceuticals, Inc. (“Anacor”), acquired by Pfizer Inc. (“Pfizer”) in 2016.

We believe our boron chemistry platform has the potential to address biological targets that have been difficult to inhibit using molecules that are solely carbon-based. Our research team is focused on bringing forward development candidates that address significant unmet needs in rare, chronic and serious infectious diseases.

In addition to our NTM development programs for epetraborole, we intend to pursue epetraborole and other compounds for global health initiatives, including melioidosis, using non-dilutive funding from sources such as public and private agencies and foundations. 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.

The below table summarizes our development plans for epetraborole:

Epetraborole			
NTM Lung Disease (oral)	PRECLINICAL	PHASE 1	PHASE 2/3
Treatment-refractory MAC (US+Global)			
Treatment-naïve MAC			
<i>M. abscessus</i>			
Global Health			
Melioidosis (IV formulation)			

The status of each of our epetraborole programs is listed below:

- *Treatment-refractory MAC lung disease*: We are initially focused on advancing our first product candidate, epetraborole, to commercialization in treatment-refractory MAC lung disease. We are conducting a pivotal Phase 2/3 study of epetraborole in treatment refractory MAC in the United States, Japan, Australia, and South Korea. For additional details, see the section titled “EBO-301: Ongoing Phase 2/3 Pivotal Clinical Trial.” We expect to complete enrollment in the Phase 2 portion of the pivotal Phase 2/3 clinical trial in mid-2023 and plan to seamlessly begin enrollment of the Phase 3 portion of the trial immediately thereafter. We expect to announce top-line data for each of the Phase 2 and Phase 3 portions of the trial approximately nine months after the completion of enrollment in each respective portion of the trial. Based on interactions with the FDA and PDMA and prior approval of Arikayce, currently the only approved therapy for treatment-refractory MAC lung disease in both jurisdictions, we believe that positive data from EBO-301 will be sufficient to support regulatory filings for approval in the United States, Japan and potentially other territories.
- *Treatment-naïve MAC lung disease*: We plan to review Phase 2 clinical data in treatment-refractory MAC lung disease from EBO-301, when available, to inform further investigation of epetraborole as part of a first-line combination regimen in treatment-naïve MAC lung disease.
- *M. abscessus lung disease*: We are currently conducting nonclinical studies as part of a dose selection study to support clinical development of epetraborole in *M. abscessus*.
- *Melioidosis*: In September 2022 we received a cost-reimbursement contract award under which we are able to receive up to \$17.8 million in non-dilutive funding in the form of cost reimbursements from the NIAID to support preclinical, Phase 1 studies, and other activities to enable advancement of epetraborole into a pivotal Phase 2/3 clinical trial for acute systemic melioidosis. In 2023, we plan to initiate nonclinical studies as part of our agreement with the NIAID to support clinical development of intravenous epetraborole in acute systemic melioidosis.

Our Strategy

We aim to develop a portfolio of therapies to treat rare, chronic, and serious infectious diseases. Key components of our strategy to achieve this goal include:

- **Advance epetraborole through clinical development in NTM lung disease with an initial focus on patients with treatment-refractory MAC lung disease.** We believe epetraborole has a high potential to bring therapeutic benefit to patients with treatment-refractory MAC lung disease as a once-daily, oral antibiotic with a novel mechanism of action. We are focused on advancing epetraborole in our ongoing pivotal Phase 2/3 trial in treatment-refractory MAC lung disease. We estimate that there are approximately 200,000 patients living with NTM lung disease in the United States (accounting for both diagnosed and undiagnosed cases), approximately 15,000 to 20,000 of whom have treatment-refractory MAC. The number of cases in Japan is among the highest in the world and is estimated to exceed the number of cases in the United States or Europe. Given the high unmet medical need for the treatment of NTM lung disease in Japan, and its major market potential, we plan to include Japanese patients in our pivotal Phase 2/3 clinical trial. Based on our discussions with the FDA and PMDA, we believe this Phase 2/3 pivotal clinical trial has the potential to be sufficient for regulatory approval in the United States and Japan. If approved, we intend to commercialize epetraborole in both the United States and Japan and potentially other territories. We are also enrolling patients from Australia and South Korea and, like Japan, we believe there are significant numbers of NTM patients in each country.
- **Develop epetraborole for treatment-naïve MAC lung disease and *M. abscessus* lung disease.** We believe epetraborole has the potential to meet the ideal target product profile (“TPP”) for treatment-naïve NTM lung disease caused by MAC due to its once-daily, oral dosing, potential tolerability profile, and novel mechanism of action. In addition, we believe that the broad-spectrum antimycobacterial activity and ideal target product profile demonstrated by epetraborole may allow for the development in other infectious diseases caused by mycobacteria, including *M. abscessus* lung infections. To expand epetraborole’s potential to address significant unmet needs for the broader NTM patient population and to maximize the market potential, we plan to review clinical data from the pivotal Phase 2/3 clinical trial in treatment-refractory MAC lung disease, when available, to inform further investigation of epetraborole in both these indications.

- **Build and scale organizational capabilities to support commercialization of epetraborole in NTM lung disease.** We have in-licensed the exclusive worldwide development and commercialization rights for epetraborole and have entered into a strategic partnership with and licensed out our rights in China, Hong Kong, Taiwan, and Macau to Bii Biosciences. We plan to build a specialized commercial organization to launch epetraborole in the United States, Japan, and potentially other territories, if approved. We also are working with several contract development and manufacturing organizations (“CDMOs”) to be launch-ready and in position to maximize the commercial potential of epetraborole should it gain regulatory approval in the United States, Japan, and potentially other territories.
- **Continue to invest in expanding our pipeline of product candidates.** We have several research programs targeting the development of novel antimicrobial compounds based on our boron chemistry platform. There is a significant need for novel NTM drugs that improve upon the currently available antibiotics that have variable efficacy, safety and tolerability profiles. We anticipate that these compounds will have the potential to be developed in combination with epetraborole and other NTM drugs for the treatment of NTM lung disease. We are also applying our boron research capabilities to discover and develop novel therapeutics for other rare or chronic infectious diseases. In addition to our internal research efforts, our strategy also includes seeking in-licensing of other development-stage compounds that are complementary to our mission.
- **Apply our expertise in antimicrobial drug design and development to other global health problems.** Our leadership team is committed to developing novel therapeutics to treat rare, chronic, and serious infectious diseases in areas of high unmet medical need. We have identified several serious infectious diseases, including melioidosis, where we believe our technology and global health development expertise has the potential to help deliver therapies to underserved populations. In September 2022, we announced receipt of a cost-reimbursement contract award under which we are able to receive up to \$17.8 million of non-dilutive funding in the form of cost reimbursements from the NIAID to support preclinical, Phase 1 studies, and other activities to enable the advancement of epetraborole into a pivotal Phase 2/3 clinical trial for acute systemic melioidosis, where we believe there is a potential to significantly lower unacceptably high mortality rates in patients. We intend to continue to collaborate with both public and private entities and foundations and are seeking non-dilutive capital to advance these global health initiatives.

Epetraborole

Key Attributes

We believe the development of epetraborole in NTM lung disease represents an attractive opportunity for the following reasons:

- **Large market opportunity.** Treatment-refractory MAC lung disease requires long-term, daily antimycobacterial therapy. There is a high unmet need in NTM lung disease and an opportunity for a safe, tolerable, effective, and oral antibacterial drug that could significantly improve patient outcomes.
- **Novel mechanism of action with a broad spectrum of antimycobacterial activity.** Epetraborole has a novel mechanism of action – inhibition of bacterial leucyl-tRNA synthetase, a bacterial target for which there are no approved drugs. Epetraborole has demonstrated broad antimycobacterial activity in preclinical studies against MAC, including but not limited to *M. avium*, *M. intracellulare*, and *M. chimaera*, which is the most common group of NTM that causes human disease (~80% cases) and is the initial focus of epetraborole’s clinical development. Furthermore, because epetraborole works through a novel mechanism of action, it is also active against strains that are resistant to other antibiotics currently used to treat NTM lung disease. Additionally, epetraborole has demonstrated potent in vitro activity as compared to *M. abscessus*, a rapid-growing NTM species that has a high unmet need for new effective antibiotics.
- **Substantial data package supports ongoing clinical studies.** Epetraborole has been investigated by AN2 in three completed Phase 1 studies and eight additional studies by Anacor and Anacor’s previous partner, GSK. The Anacor and GSK studies, in intravenous and oral formulations of epetraborole, included six Phase 1 and two truncated Phase 2 clinical trials in over 200 subjects at a wide range of clinical doses. We are currently conducting a pivotal Phase 2/3 clinical trial in treatment-refractory MAC lung disease. In parallel, we plan to initiate enrollment this year in a thorough QT (“TQT”) study (EBO-104) and a Phase 1 study evaluating the pharmacokinetics of epetraborole in patients with varying degrees of hepatic impairment (EBO-105). We believe that these additional studies, once completed, will support NDAs in the United States and Japan if a positive outcome in the Phase 3 portion of EBO-301 is achieved.

- **Compatibility with guideline-based combination treatments.** The current standard of care therapy for NTM lung disease includes administration of three or more antimycobacterial agents, the combination of which improves efficacy, shortens the duration of therapy, and significantly reduces the chance that resistance to individual drugs would develop. Given epetraborole's novel mechanism of action and low potential for drug-drug interactions with existing antibiotics, we believe it has the potential to become an important component of a multi-drug treatment regimen for patients living with treatment-refractory MAC lung disease. Additionally, in nonclinical pharmacokinetic models of NTM MAC infection, epetraborole added on top of a triple-drug guideline-based regimen demonstrated significantly improved bacteria reductions vs. guideline therapy alone.
- **Twelve years of regulatory exclusivity anticipated in the United States, if approved.** In addition to current and potential future patent protection in the major geographies, epetraborole, if approved, is expected to receive 12 years of post-approval marketing exclusivity in the U.S. from its existing QIDP and orphan drug designations.

Mechanism of Action

Epetraborole is a 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, which prevents the synthetic site from attaching leucine to tRNA^{Leu} thus shutting down tRNA leucylation and leading to a block in protein synthesis.

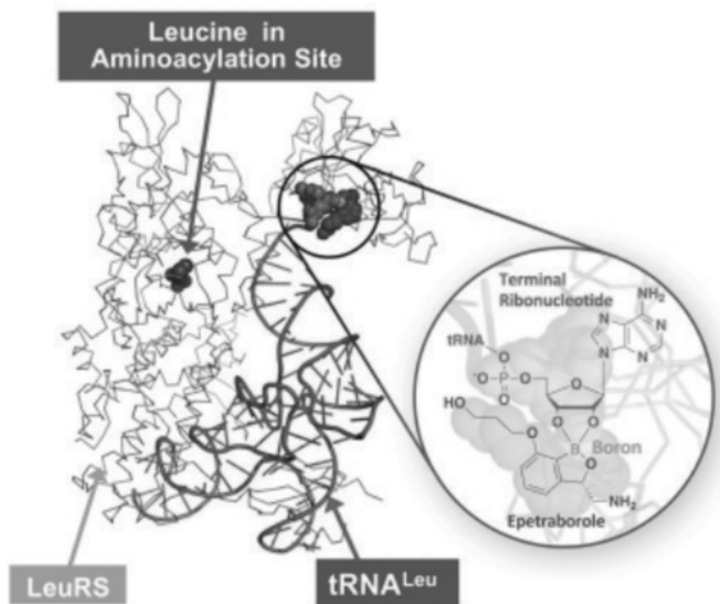


Figure A. Epetraborole inhibits the protein synthesis enzyme leucyl-tRNA synthetase, or LeuRS, by binding to the terminal adenosine ribose of tRNA^{Leu} in the editing site.

As shown in Table 1 below, epetraborole has demonstrated antimicrobial activity against a broad panel of 51 isolates of MAC, with minimum inhibitory concentrations, or MICs, of 0.25 mg/ml to 8 mg/ml. Because epetraborole works via a novel mechanism of action, it 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 - 8	0.25 - >64	8 - >64
MIC ₅₀	2	1	16
MIC ₉₀	8	4	64

Table 1. Antimicrobial activity of epetraborole, clarithromycin and amikacin against 51 isolates of MAC including 17 *M. intracellulare* isolates, 1 *M. avium* isolate, 3 *M. avium* complex isolates, 20 *M. avium* subsp. *hominissuis* isolates, and 10 *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. Inmed Incorporated reported net sales of Arikayce of approximately \$245.4 million in 2022 (\$186.0 million in the United States, \$56.5 million in Japan, and \$2.9 million in Europe and the rest of the world), a 30% increase over 2021. 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. 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.

Epetraborole Development Program

EBO-301: Ongoing Phase 2/3 Pivotal Clinical Trial

In June 2022, we announced the initiation of our pivotal Phase 2/3 trial evaluating epetraborole in treatment-refractory MAC lung disease. We are enrolling patients with treatment-refractory MAC lung disease in this double-blind, placebo-controlled trial, with planned enrollment of 80 patients in the Phase 2 portion and approximately 234 patients in the Phase 3 portion (the final number of patients for the Phase 3 portion to be determined based on Phase 2 portion of the trial and assuming an 80% evaluability rate in the primary analysis population). To date we have activated nearly 60 sites worldwide. We designed this trial to include Japanese patients in sufficient numbers to support regulatory approval in Japan.

The Phase 2 portion of the trial consists of one cohort of approximately 40 patients treated with epetraborole plus an optimized background regimen ("OBR") consisting of two or more standard-of-care drugs, and one cohort of approximately 40 patients treated with placebo plus an OBR. The primary objectives in the Phase 2 portion of the trial are to assess the measurement properties of a novel patient-reported outcome ("PRO") instrument and to provide validation evidence in treatment-refractory MAC lung disease including determination of clinical response, microbiological response, and safety of oral epetraborole plus OBR compared to placebo plus OBR. Data from the Phase 2 portion of the trial will be used to inform the clinical response measures evaluated in the Phase 3 portion of the trial. While the Phase 2 portion of the trial is not powered for statistical significance, we believe these data will provide a meaningful indication of epetraborole's activity in humans in treatment-resistant MAC lung disease.

The primary objective in the Phase 3 portion of the trial will be to determine if epetraborole plus OBR is superior to placebo plus OBR in clinical response or microbiological response. The trial includes four PRO tools for measuring clinical improvement, including the Macro2 PRO, which we developed specifically for this trial. To support a U.S. NDA, the primary endpoint in the Phase 3 part of the trial may include a symptom-based clinical response measure as measured by a PRO at month six or culture conversion at month six. The primary endpoint will be confirmed upon FDA review of Phase 2 data. Based on our discussions with the PMDA, we expect that the primary endpoint for the Phase 3 portion of the trial in Japan will be culture conversion at month six, with supportive data on durability response required to support marketing authorization. We expect that secondary endpoints will include other microbiological, clinical, or safety measures.

We expect that the Phase 3 portion of the trial will consist of one cohort of approximately 156 patients treated with epetraborole plus an OBR and one cohort of approximately 78 patients treated with placebo plus an OBR. These anticipated enrollment figures may change as our sample-size and trial-design will be informed by the ongoing Phase 2 portion of our trial.

We expect to complete enrollment in the Phase 2 portion of the pivotal Phase 2/3 clinical trial in mid-2023 and plan to seamlessly begin enrollment of the Phase 3 portion of the trial immediately thereafter. We expect to announce top-line data for each of the Phase 2 and Phase 3 portions of the trial approximately nine months after the completion of enrollment in each respective portion of the trial.

Based on interactions with FDA, the PMDA, and the prior approval of Arikayce in both jurisdictions, we believe that positive data from EBO-301 has the potential to be sufficient to support regulatory filings for approval in the United States, Japan and potentially other countries.

An overview of our pivotal Phase 2/3 clinical trial design is below in Figure B.

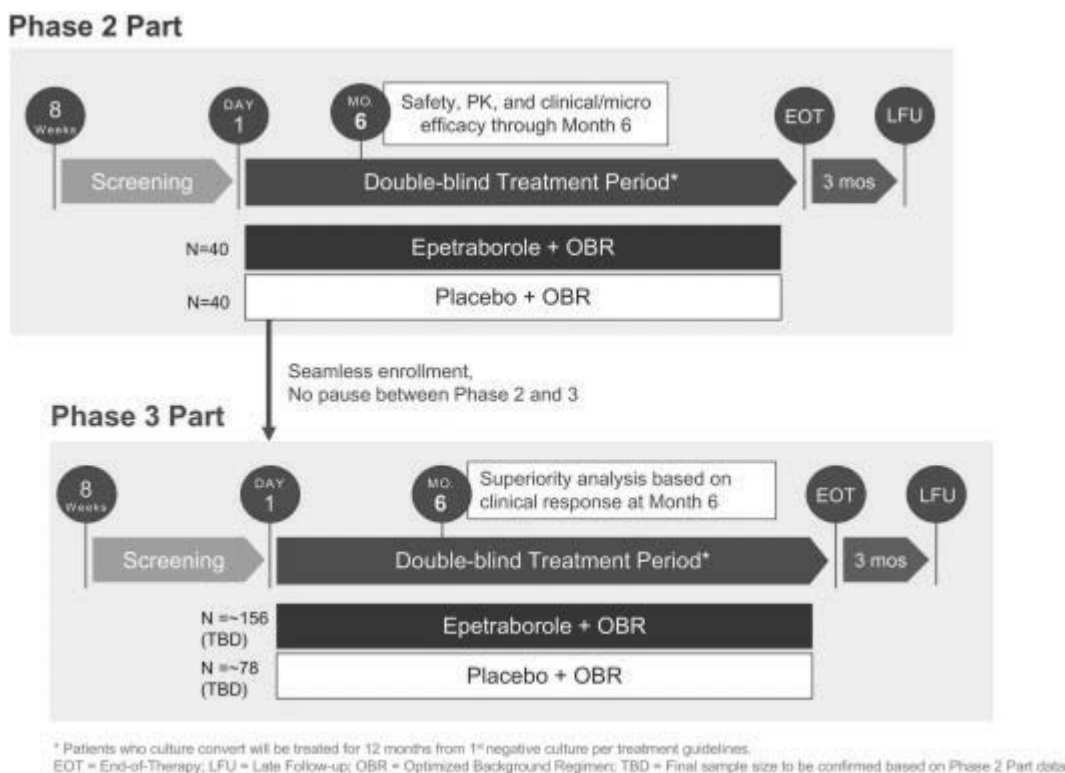


Figure B. Pivotal Phase 2/3 pivotal clinical trial of epetraborole in treatment-refractory MAC lung disease

Clinical and Non-Clinical Data Package to Support Regulatory Filings

In addition to the ongoing EBO-301 trial, we have completed three Phase 1 studies and are in the process of initiating two additional Phase 1 studies: a TQT study and a study evaluating the pharmacokinetics of epetraborole in subjects with varying degrees of hepatic impairment. We believe that these studies, once completed, in conjunction with a positive outcome in EBO-301, will support marketing applications in the United States, Japan and other potential markets.

Ongoing clinical studies

- In 2022, we initiated our pivotal Phase 2/3 trial evaluating once-daily, oral epetraborole for treatment refractory MAC lung disease. See the section titled “*EBO-301: Ongoing Phase 2/3 Pivotal Clinical Trial.*”
- In 2023, we plan to initiate enrollment in a Phase 1 TQT study (EBO-104) and a Phase 1 study evaluating the pharmacokinetics of epetraborole in subjects with varying degrees of hepatic impairment (EBO-105).

Completed clinical studies

- In previous development work with epetraborole conducted by Anacor and GSK, its pharmacokinetics was well characterized using substantially higher doses.
- In 2021, we completed EBO-101, a dose-ranging study in healthy volunteers, which assessed the pharmacokinetics and safety of oral epetraborole doses relevant for treatment-refractory MAC lung disease and administered for 28 days, including a food-effect cohort. Results from our Phase 1 clinical trial showed the exposures of epetraborole in alveolar (lung) macrophages, the human cells that are infected with mycobacteria in NTM lung disease, was approximately five-fold higher than in plasma. These results suggest therapeutically relevant exposures of epetraborole may be achieved in these macrophages with orally administered doses that are substantially lower than the maximum tolerated doses and exposures in previous trials.
- In 2022, we completed EBO-102, which assessed the pharmacokinetics of epetraborole in subjects with varying degrees of renal function.
- In 2022, we completed EBO-103, which assessed the pharmacokinetics of epetraborole in Japanese subjects to support initiation of clinical trials in Japan.

Completed non-clinical studies

We have completed toxicology and safety pharmacology studies, including chronic toxicology studies by oral administration in both rats (for a period of six months) and non-human primates (for a period of nine months) where epetraborole was tolerated at much higher exposures compared to the once-daily dose of 500 mg that we intend to use to treat patients with treatment-refractory MAC lung disease in our Phase 2/3 pivotal clinical trial. Additionally, we recently completed the last of the three standard reproductive toxicity studies (segment 3) that are necessary to support regulatory filings. No findings of concern were identified.

We have completed non-clinical studies to characterize the antimicrobial activity of epetraborole in vitro and in animal models. In one study, we tested the antimicrobial activity of epetraborole against 51 isolates of MAC compared to clarithromycin and amikacin resulting in an MIC₉₀ of 8 µg/mL. Furthermore, we recently completed testing of epetraborole against 110 MAC clinical isolates from Japan and an MIC₉₀ of 4 µg/mL was reported. These studies demonstrated that, preclinically, epetraborole has broad anti-mycobacterial activity as compared to MAC isolates both regionally as well as against resistant strains of amikacin and clarithromycin. In another study, we compared epetraborole to clarithromycin in a chronic model of MAC lung disease in mice. This study indicated that epetraborole has improved antibacterial activity at all doses as compared to a 250 mg/day clarithromycin human dose equivalent. A third study in a mouse model indicated that epetraborole showed a superior ability to decrease colony forming units as monotherapy and in combination with standard of care versus standard of care alone.

Chemistry, Manufacturing and Controls

In 2022, we commenced work to enable manufacturing of registration batches of epetraborole drug substance and drug product. In 2023, we plan to complete drug substance and drug product registration batches and initiate stability studies that are necessary to support NDA filings. Furthermore, we have initiated work with two additional suppliers for a key intermediate needed to manufacture epetraborole, providing redundancy and risk mitigation. Our goal is to be NDA-ready and to maximize commercial launch potential.

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.

Future Development of Epetraborole

We plan to study epetraborole as part of first-line combination treatment of treatment-naïve patients with MAC lung disease. We believe that the addition of epetraborole to first-line treatment has the potential to significantly improve clinical and/or microbiological response rates without increasing the incidence of adverse events. We plan to review treatment-refractory MAC lung disease pivotal Phase 2/3 clinical data to inform further investigation of epetraborole as a first-line therapeutic option in MAC lung disease.

We also intend to pursue development of epetraborole as a first-line therapy in *M. abscessus* lung disease, which represents a smaller subset of NTM (~20% of NTM patients) but also has a high unmet need. We are currently conducting nonclinical studies as part of dose selection to support clinical development of epetraborole in this disease. Current treatments for *M. abscessus* lung disease have poor efficacy (~50%), are often delivered by intravenous infusion and have significant tolerability and safety issues. We believe that oral epetraborole, in combination with other drugs, has the potential to treat *M. abscessus* lung disease based on its *in vitro* and *in vivo* potency against multiple isolates.

Epetraborole Regulatory Exclusivity

As an orphan and QIDP-designated product, if approved in the United States, we anticipate 12 years of regulatory exclusivity for treatment-refractory MAC lung disease, independent of any applicable patent protection we may acquire. During the first ten years, the FDA would be prohibited from approving any 505(b)(2) or abbreviated new drug applications for any use of epetraborole. In years 11 and 12, the FDA would be prohibited from approving another company's epetraborole for treatment-refractory MAC lung disease. If approved in Japan, we anticipate at least eight years of exclusivity, independent of any applicable patent protection that we may acquire.

Our AN2 Drug Discovery Platform

Boron-Based Chemistry Platform Enables the Targeting of Novel Biological Targets

Our core technology approach is based on the use of boron chemistry platform for our research and development initiatives. Boron has both an ability to bind with biological targets through a reversible covalent bond and the potential to address biological targets that have been difficult to inhibit using traditional carbon-based molecules.

Historically, the starting points for small molecule antibiotic drug discovery have been based on natural products or peptides. These molecules typically do not contain boron, which has led to a lack of focus on boron-based compounds and a reduced understanding of the physical and biological properties of boron, thereby limiting the incorporation of this element into drug products. Additionally, boron-based compounds have been historically difficult to synthesize, but recent advancements in the science and practice of boron-based drug research have allowed for its incorporation in drug discovery efforts. In particular, advanced computational techniques have been developed to improve the understanding of boron and its interaction with key biological targets relevant to drug discovery efforts. Additionally, new tools and methods have been developed to facilitate the creation of novel boron-containing compound families. These unique compound families expand the universe of biological targets that can be addressed by small molecule boron-based compounds.

Boron-based inhibitors typically are highly selective for their biological target, thereby minimizing their potential off-target effects. The ability to modify boron's reactive center, an activity known as tuning, allows drug developers to modulate key properties of the resulting compounds. Properties such as solubility, permeability, molecular charge at different pH values, and metabolic stability, may be designed such that inhibitors can reach any compartment in the body.

Previous work at Anacor led to the generation of a class of boron compounds known as fused boron heterocyclic compounds that demonstrated greatly improved drug-like properties. This work enabled the discovery of compounds that inhibited aminoacyl transfer RNA, or tRNA, synthetases in a novel way that is dependent on boron for activity. One of these compounds, tavaborole, targets a fungal aminoacyl tRNA synthetase and is FDA-approved as Kerydin to treat onychomycosis of toenails. Epetraborole is a boron-containing analog of tavaborole and was designed to specifically target bacterial leucyl-tRNA synthetase. GSK is also researching a leucyl-tRNA synthetase inhibitor that was specifically designed to target *Mycobacterium tuberculosis* ("TB") by scientists at Anacor. The lead chemist and biologist on this program are employed by AN2 Therapeutics. Although this TB-specific boron-based leucyl-tRNA synthetase inhibitor, GSK3036-656, is exceptionally potent against TB, it is devoid of MAC activity. Recently GSK reported positive Phase 2 data for GSK3036-656 in a 14-day early bactericidal study in TB patients whereby a single oral dose of 30 mg per day reduced bacteria in the sputum of patients nearly to the same levels as daily therapy of the standard four-drug regimen. While TB is a different disease to NTM lung disease, it does demonstrate proof of concept of a LeuRS inhibitor in a lung infection caused by a mycobacterium.

Expansion of Our Portfolio of Product Candidates

We have deep expertise in boron chemistry as exemplified by our team's history of developing epetraborole and we are actively pursuing the identification of additional antimicrobial product candidates that leverage our boron chemistry capabilities. Once identified, we plan to develop these candidates targeting NTM lung disease and other rare and chronic infectious diseases. We are also selectively evaluating in-licensing opportunities of development-stage candidates addressing rare and chronic infectious diseases consistent with our corporate strategy.

Our Global Health Initiatives

Our leadership team is committed to applying our know-how to help solve some of the most challenging infections in global health. Our intent is to fund these efforts primarily through non-dilutive funding from sources such as public and private agencies and foundations.

Melioidosis

Our near-term global health priority is melioidosis, 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. *B. pseudomallei* is endemic to tropical regions of the world with the majority of 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 macrophages, an important element in melioidosis. 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, six 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 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 announced receipt of a cost-reimbursement contract award under which we are able 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 a pivotal Phase 2/3 clinical trial for acute systemic melioidosis. The project has been funded in whole with nondilutive federal funds from the NIAID, NIH, and the Department of Health and Human Services.

In addition to our work with the NIAID on our melioidosis program, we also have partnered with the Mahidol Oxford Tropical Medicine Research Unit in Thailand and Colorado State University on preclinical research for our melioidosis program. We believe these partners provide substantial technical and capital resources to advance the melioidosis program and provide material benefits to our company and 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, or 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 Bii Biosciences Limited

In November 2019, we entered into a license agreement, or the Bii Biosciences License Agreement, pursuant to which we granted Bii 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 Bii Bioscience. Further, neither we nor Bii Biosciences can develop a competing product that is directed to the same target as a licensed compound during the term of the Bii 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 Bii Biosciences has delivered a proof of concept acceptance notice, Bii Biosciences has the final decision-making authority, subject to certain veto rights of ours. Upon commencing development, Bii 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.

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, 2022, 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, or 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.

As of December 31, 2022, we exclusively licensed three U.S. patents, 40 foreign patents, and approximately four pending foreign patent applications, covering our key programs and pipeline. We do not own any issued patents. We own three pending PCT patent applications, which are not eligible to become issued patents until, among other things, we file a non-provisional patent application with the USPTO or a foreign patent office.

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.

Epetraborole Product Candidate

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 two granted patents in the United States, from the in-licensed patent portfolio, covering compositions of matter of a genus of molecules, and the epetraborole product candidate molecule specifically, pharmaceutical compositions, and methods of treating a bacterial-associated or fungal-associated disease. We have granted foreign patents from the in-licensed patent portfolio from Argentina, Armenia, Australia, Azerbaijan, Belgium, Canada, China, Denmark, Finland, France, Germany, Hong Kong, India, Indonesia, Ireland, Israel, Italy, Japan, Kyrgyz Republic, Malaysia, Mexico, Moldova, Netherlands, New Zealand, Norway, Russian Federation, Singapore, South Africa, South Korea, Spain, Sweden, Tajikistan, Turkey, United Kingdom, Uruguay, and Vietnam. Patent applications from the in-licensed patent portfolio are pending in Bangladesh, Brazil, Pakistan, South Africa, Thailand, and Venezuela. Patents and patent applications, if granted, in our in-licensed patent portfolio are expected to expire in 2028, without taking potential patent term extensions or patent term adjustment into account.

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 key 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.

We are currently developing epetraborole for treatment-refractory NTM lung disease caused by MAC isolates. If approved, epetraborole would compete with Insmed's Arikayce, which is the only currently approved therapy for patients with this condition. Other drugs used to treat these patients include generic drugs such as macrolides (clarithromycin and azithromycin), ethambutol, rifabutin, fluoroquinolones such as levofloxacin, bedaquiline, linezolid, and clofazimine. There are also a number of product candidates in clinical development by third parties that are intended to treat NTM lung disease, including mid- to late-stage product candidates such as SPR720 from Spero Therapeutics, Inc., RHB-204 from Redhill Biopharma Ltd., and omadacycline from Paratek Pharmaceuticals, Inc. We also expect that epetraborole, if approved, would compete with future and current generic versions of marketed antibiotics.

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 New Drug Application, or 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 products and 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, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign 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 preclinical laboratory tests, animal studies, and formulation studies in accordance with FDA's Good Laboratory Practice requirements and other applicable regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board, or 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 practices, or GCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- preparation of and submission to the FDA of an NDA after completion of any or all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- 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, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indication(s) for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. 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. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. 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. 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. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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 or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- **Phase 2:** The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- **Phase 3:** The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical 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 investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be conducted after initial marketing approval and may be 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 cGMP requirements. 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.

While the IND is active and before approval to commercialize, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report 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.

In addition, during the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, before an NDA is submitted, and at other times as requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical, and other nonclinical 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. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. 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. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are 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, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the filing date to complete a standard review of an NDA for a drug that is a new molecular entity, and of ten months from the date of NDA receipt to complete a standard review of an NDA for a drug that is not a new molecular entity.

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. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and 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 also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

In addition, the Pediatric Research Equity Act, or 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 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 safe and effective. The sponsor or 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.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the Fast Track program is intended to expedite or facilitate the process for reviewing new products that 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. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a Fast Track designated product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. A Fast Track designated product may also be eligible for rolling review, where 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.

A marketing application for a drug submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review. A product candidate is eligible for priority review if it is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For new-molecular-entity NDAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date, or with respect to non-new-molecular-entity NDAs, within six months of the NDA receipt date.

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may utilize an accelerated approval pathway upon a determination that the product 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 accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for 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 designation, and the accelerated approval pathway 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 FDA review or approval will not be shortened.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease 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, including a full NDA, to market the same drug for the same use for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Exclusivity

The FDA provides periods of non-patent regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. Five years of exclusivity are available to new chemical entities, or NCEs. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (i.e., formed by the chemical interaction of two compounds), chelate (i.e., a chemical compound), or clathrate (i.e., a polymer framework that traps molecules), of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an Abbreviated New Drug Application, or ANDA, or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. Five-year and three-year exclusivity will not delay the submission or approval of a 505(b)(1) NDA; however, an applicant submitting a 505(b)(1) 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 efficacy.

In addition, under the Generating Antibiotic Incentives Now, or 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 antibiotic or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (1) an antibiotic 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 to established and maintained by the FDA. A sponsor must request such designation before submitting a marketing application. Upon approving a marketing application for a QIDP-designated product, the FDA will extend by an additional five years any non-patent marketing exclusivity period awarded. 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.

Post-approval Requirements

Drug 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 or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors 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 cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP 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 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 clinical studies;

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product 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.

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, purity, and potency 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, in their independent professional medical judgment, 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. 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. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

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.

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 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, or 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 beginning in 2022, 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, or 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; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; 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 Innovation at CMMS 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. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which was temporarily suspended from May 1, 2020 through December 31, 2021, and reduced payments to several types of Medicare providers. 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. By way of example, the American Taxpayer Relief Act of 2021, effective January 1, 2024, would eliminate the statutory cap on rebate amounts owed by drug manufacturers under the Medicaid Drug Rebate Program, or MDRP, which is currently capped at 100% of the AMP for a covered outpatient drug. Further, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices.

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 and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. 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

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including Health Insurance Portability and Accountability Act, or HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure, and protection of health-related and other personal information could 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, or CCPA, the California Privacy Rights Act, or CPRA, and the General Data Protection Regulation, or 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 and may not have the same effect, thus complicating compliance efforts. Failure to comply with these 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, may 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, 2023, we had 35 full-time employees and one part-time employee, consisting of clinical operations, clinical development, research, development, manufacturing, regulatory, quality, finance, and operational personnel. Thirteen of our employees hold Ph.D. or M.D. degrees, or both. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

We recognize that our continued ability to attract, retain, and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- ***Talent development, compensation, and retention:*** We strive to provide our employees with a rewarding work environment, including the opportunity for growth, success, and professional development. We provide a competitive compensation and benefits package, including bonus and equity incentive plans, a 401(k) plan—all designed to attract and retain a skilled and diverse workforce.
- ***Health and safety:*** We support the health and safety of our employees by providing comprehensive insurance benefits, an employee assistance program, company-paid holidays, a personal time-off program, and other additional benefits which are intended to assist employees to manage their well-being.
- ***Inclusion and diversity:*** We are committed to efforts to increase diversity and foster an inclusive work environment that supports our workforce.

COVID-19 Impact on Facilities

We have implemented policies that enable our employees to work remotely, and such policies may continue for an indefinite period. As prescribed by the U.S. Center for Disease Control, state and local guidelines, we have over time also implemented various safety protocols for all on-site personnel, including the requirements to wear masks, suspend all non-essential travel for our employees, and maintain social distance. We continue to evaluate our protocols and practices as the global response to the COVID-19 pandemic continues to evolve. While we are partially operating virtually to align with local COVID-19 guidelines, we believe our operational needs are being met for the time being. To date, we have not experienced any material impact on our ability to operate our business. We plan to periodically reassess the impact of COVID-19 on our facility needs.

Securities Exchange Act Reports

The Company maintains a website at the following address: [https:// www.an2therapeutics.com/](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 of 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.

Our business involves significant risks, some of which are described below. 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.

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. Our initial product candidate, epetraborole, is currently in clinical development. Our net loss was \$41.0 million and \$21.5 million for the year ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of \$89.7 million. We have funded our operations to date primarily with proceeds from our initial public offering (“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 studies, manufacturing, clinical trials, and general and administrative costs associated with our operations. We have initiated Phase 2/3 clinical development of epetraborole, and we have not completed development of any product candidates. 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 epetraborole;
- 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 epetraborole and any of our future product candidates that successfully complete clinical trials;
- ultimately establish sales, marketing, and distribution infrastructure and scale up external manufacturing capabilities as we move into later-stage clinical trials and look 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, and management, and compliance information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional 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 epetraborole and any future 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 any delays in the initiation and completion of our clinical trials or the development of epetraborole and any of our future 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 may encounter unforeseen expenses, difficulties, complications, delays, and other known or unknown factors in achieving our business objectives. 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 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 epetraborole;
- the costs, timing, and outcome of regulatory review of epetraborole and any of our future product candidates;
- 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 epetraborole or any future product candidates that receive marketing approval;
- the pricing and revenue, if any, received from commercial sales of epetraborole or any future product candidates that receive marketing 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, epetraborole and any of our future 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 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 epetraborole or any of our future 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 epetraborole or any future 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 epetraborole or any future product candidate 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. In September 2022, we received a cost-reimbursement contract award under which we are able to receive up to \$17.8 million from the 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. 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 Current and Future Product Candidates

We depend to a large degree on the success of epetraborole, which is in clinical development, but for which we have not completed our pivotal Phase 2/3 clinical trial. If we do not obtain regulatory approval for and successfully commercialize epetraborole or any of our future 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 invested a significant portion of our efforts and financial resources on the development of our initial product candidate, epetraborole, as a treatment for serious infections caused by NTM lung disease resulting from MAC bacteria. We expect that a substantial portion of our efforts and expenses over the next few years will be devoted to the development of epetraborole. As a result, our business currently depends heavily on the successful development, regulatory approval, and, if approved, commercialization of epetraborole or any of our future 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 epetraborole or any of our future product candidates are, and will remain, subject to comprehensive regulation by the FDA, the PMDA, the EMA, the TGA, and other comparable foreign regulatory authorities. To date, we have completed three clinical trials, a Phase 1 dose-ranging study of epetraborole in Australia, a Phase 1 safety and pharmacokinetics study of oral epetraborole in healthy volunteers in Japan, and a Phase 1 renal impairment study in the United States. We are currently enrolling patients in a pivotal Phase 2/3 clinical study of epetraborole in the United States, and are planning on initiating two additional Phase 1 studies in 2023. Before obtaining regulatory approvals for the commercial sale of epetraborole and any future product candidates, we must demonstrate through preclinical and nonclinical studies and clinical trials that the product candidate is safe and effective for use in the 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. Failure to obtain regulatory approval for epetraborole and our future product candidates in the United States or other territories will prevent us from commercializing and marketing such product candidates. The success of epetraborole and our future product candidates will depend on several additional factors, including:

- successful completion of preclinical and nonclinical studies and requisite clinical trials;
- performing preclinical studies and clinical trials in compliance with the FDA, the PMDA, the EMA, the TGA, or any comparable regulatory authority requirements;
- receipt of marketing approvals from applicable regulatory authorities;
- the ability to manufacture sufficient quantity of product for development, clinical trials, or potential commercialization;
- obtaining marketing 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, or REMS, program;
- obtaining and maintaining patent, trademark, and trade secret protection, and regulatory exclusivity for epetraborole and any future 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
- approval of our future INDs.

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 epetraborole or any of our future 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 serious infections (including different forms of NTM lung disease). We may not be able to develop product candidates that are safe and effective. 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 marketing approval or limit market acceptance or reimbursements from third-party payors. If we do not successfully develop and commercialize epetraborole and/or any future 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.

Success in preclinical or nonclinical studies or initial clinical trials may not be indicative of results in future clinical trials. To support our clinical development strategy for epetraborole, we are relying, in part, on clinical data from prior clinical trials conducted by Anacor and GlaxoSmithKline plc which were not conducted in patients with NTM. Differences with these prior clinical trials evaluating epetraborole will limit our use of prior clinical data for epetraborole and our ability to support our proposed clinical trial plan for epetraborole with the FDA.

Success in preclinical or nonclinical studies or initial clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the safety, tolerability, and efficacy of a product candidate. These clinical trials were not conducted in patients with NTM lung disease nor were they conducted over durations greater than 14 days, shorter than the typical treatment of patients with NTM lung disease. Epetraborole and our future product candidates may fail to show the desired safety, tolerability, and efficacy in clinical development despite promising results in preclinical studies or having successfully advanced through initial clinical trials in healthy volunteers. For instance, with respect to epetraborole, we cannot guarantee that the dose used in our ongoing pivotal Phase 2/3 clinical trial will be safe, tolerable, or effective. We cannot guarantee that the dose selected will be validated in our ongoing pivotal Phase 2/3 clinical trial in patients with treatment-refractory MAC lung disease. The ongoing pivotal Phase 2/3 clinical trial will be the first evaluation of epetraborole in patients with MAC lung disease and specifically in treatment-refractory patients.

In addition, safety, tolerability, and pharmacokinetic observations of epetraborole, used as monotherapy, in previous clinical trials conducted by Anacor and GSK, including penetration into alveolar (lung) macrophages and the long-term effects on red blood cell-related hematological parameters, such as hemoglobin and reticulocytes, may not be predictive of safety or efficacy results in our ongoing pivotal Phase 2/3 clinical trial. There are significant differences in the epetraborole Phase 1 clinical trial conducted by Anacor and the five Phase 1 clinical trials and two Phase 2 clinical trials conducted by GSK compared to the clinical trial design of our ongoing pivotal Phase 2/3 clinical trial. Other differences with these prior clinical trials, including differences in patient population, targeted indication, drug product formulation, and trial design, will limit our use of prior clinical data for epetraborole and our ability to support our clinical trial plan for epetraborole with the FDA.

We are enrolling patients in a single pivotal Phase 2/3 clinical trial as the basis for submission to the FDA for product approval of epetraborole, and there can be no assurance that the single study will be sufficient for product approval.

The FDA generally requires two well-controlled Phase 3 clinical trials for product approval. However, in some cases the FDA has not required two Phase 3 clinical trials for product approval. For example, amikacin liposome inhalation suspension, marketed by Insmid Incorporated as Arikayce, was approved to treat treatment-refractory NTM lung disease caused by MAC on the basis of a single Phase 3 clinical trial. We are conducting a single pivotal Phase 2/3 clinical trial to support approval of epetraborole in MAC, but there can be no assurance that the FDA will not require additional clinical trials for approval of epetraborole.

The data we have collected and continue to collect in our Phase 1 programs, and from the Phase 2 portion of our pivotal Phase 2/3 clinical trial may not support continued clinical investigation due to insufficient clinical responses or occurrence of adverse safety events or may lead to adjustments in trial design, rendering it not feasible to conduct or not acceptable to the FDA or to us, including adjustments to clinical trial endpoints and sample size for the Phase 3 portion of our initiated pivotal Phase 2/3 clinical trial. Our current trial design for our pivotal Phase 2/3 clinical trial includes a Phase 2 portion that we expect will inform endpoint selection for the Phase 3 portion of the trial and gather data on the treatment effects of epetraborole-containing regimens, if any, which may require increases or other adjustments in the sample size for the Phase 3 portion and which could result in a delay in topline results and additional costs for the Phase 3 portion of the trial.

The FDA can recommend study design element changes at any time, including, for example, change of endpoints, eligibility criteria, or statistical analyses. For example, Arikayce, the only drug currently approved by the FDA for treatment-refractory NTM lung disease caused by MAC, was approved based on the primary endpoint of microbiological culture conversion, whereas we will be required to demonstrate efficacy based on clinical response endpoints. As a company, we have limited experience designing NTM clinical trials and have no experience conducting clinical trials in the United States and may be unable to design and execute a clinical trial to support regulatory approval. In addition, the design and results of a pivotal Phase 2/3 clinical trial may not be sufficient to determine whether the trial results will support approval, since factors such as an insufficient dosage regimen or flaws in the design of a clinical trial may not become apparent until the clinical trial is in progress.

There is a high failure rate for drug and biologic products 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, a Phase 2 clinical trial conducted by GSK to evaluate epetraborole in patients with complicated urinary tract infections was terminated early due to microbiological findings of resistance to epetraborole, which caused GSK to discontinue its epetraborole development program. In addition, data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. Furthermore, the dosing duration for administering epetraborole in humans has been limited to a maximum of 28 days in previous clinical trials. The study drug dosing duration in our pivotal Phase 2/3 clinical trial is up to 16 months total. The longer dosing duration expected in our pivotal Phase 2/3 clinical trial, as well as the use of epetraborole in patients with NTM lung disease, may increase the risk of hematological abnormalities or the potential for the emergence of new, unknown treatment-emergent adverse events. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations, and prospects.

If clinical trials of epetraborole or any future product candidate that we may advance to clinical trials fail to demonstrate safety, tolerability, and/or efficacy to the satisfaction of the FDA, the PMDA, the EMA, the TGA, 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 epetraborole or any future product candidate.

We may not commercialize, market, promote, or sell any product candidate without obtaining marketing approval from the FDA, the PMDA, the EMA, the TGA, or other comparable regulatory authorities, and we may never receive such approvals. It is impossible to predict when or if epetraborole or any future product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of epetraborole or any future product candidates, we must complete preclinical and nonclinical development and conduct extensive clinical trials to demonstrate the safety, tolerability, 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 marketing approval of their products.

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 marketing approval or commercialize epetraborole or any of our future product candidates, including, but not limited to:

- the FDA, the PMDA, the EMA, the TGA, or other comparable regulatory authorities may disagree as to the design or implementation of our clinical trials, which may result in changes to our planned clinical trial design and potential target clinical outcomes, which could otherwise delay or otherwise negatively impact our ability to complete our clinical plans effectively;
- regulators or institutional review boards may not 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 contract research organizations, or 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;
- clinical trials for epetraborole or any of our future product candidates may produce negative or inconclusive results;
- we may be unable to successfully defeat bacterial resistance mechanisms in our initiated epetraborole pivotal Phase 2/3 clinical trial, which may require early termination of the trial or abandonment of our epetraborole program;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- enrollment in the pivotal Phase 2/3 clinical trial of epetraborole and clinical trials of any future product candidates 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 epetraborole and any of our future 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;
- the cost of clinical trials of epetraborole or any of our future product candidates may be greater than we anticipate;
- the FDA, the PMDA, the EMA, the TGA, 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 epetraborole or any of our future product candidates or other materials necessary to conduct clinical trials of such product candidates may be insufficient or inadequate;
- epetraborole or our future product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA, the PMDA, the EMA, the TGA, 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 (for instance, if regulatory authorities required us to conduct a separate Phase 2 clinical trial prior to the initiation of a Phase 3 clinical trial, rather than the ongoing pivotal Phase 2/3 clinical trial as designed) or other testing of epetraborole or any of our future product candidates beyond the studies that we currently contemplate, if we are unable to successfully complete clinical trials or other testing of epetraborole or any of our future 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 marketing approval for our product candidates;
- not obtain marketing 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 marketing approval.

Our product development costs may also increase if we experience delays in testing or marketing approvals and we may be required to obtain additional funds to complete clinical trials. 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 epetraborole or our future product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize epetraborole or our future 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 epetraborole or any of our future product candidates.

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

We are developing epetraborole to treat bacterial infections. The bacteria responsible for these infections evolve quickly and may readily transfer their resistance mechanisms within and between species. Prescription or use of epetraborole or our product candidates, if approved, may depend on the type and rate of resistance of the targeted bacteria. Although we do analyze the potential of epetraborole and any future product candidates to develop resistance and only select those that we believe have low resistance potential, we cannot predict whether or when bacterial resistance to epetraborole or future product candidates may develop should they obtain market approval and be broadly prescribed. For example, clinical resistance to epetraborole as a monotherapy was observed by GSK in its Phase 2 trial for the treatment of complicated urinary tract infection, and we cannot guarantee that clinical resistance will not be observed in any of our future clinical trials with epetraborole. 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.

Epetraborole or any of our future 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 marketing approval.

Epetraborole is not yet approved by the FDA, the PMDA, the EMA, the TGA, or any other regulatory agency and has not yet been tested extensively in patients. In previous development programs evaluating epetraborole, which largely used higher doses administered intravenously and orally, subjects and patients receiving epetraborole experienced drug-related side effects. For example, the most common drug-related adverse events observed in oral administration of epetraborole in humans were gastrointestinal in nature. Further, in a 26-week study conducted with epetraborole in rats and in a 39-week study conducted with epetraborole in non-human primates, safety observations of reduced hematocrit, hemoglobin, and other associated red blood cell-related parameters (red cell distribution width, mean corpuscular volume, mean corpuscular hemoglobin concentration, mean corpuscular hemoglobin) levels were observed, which remained below normal during the recovery period of the study while other blood cell parameters returned to normal levels. In a Fertility and Embryo-Fetal Development study of epetraborole in rats, there were no external fetal malformations or variations, no soft-tissue (visceral or fixed-head) fetal malformations or variations, and no skeletal fetal malformations attributed to administration of epetraborole at any dose level evaluated in the study. However, there were multiple maternal and fetal adverse events, including reduced mean maternal body weight during gestation, reduced mean fetal weight, increased mean total resorptions per litter and higher mean post-implantation loss at the highest dose level tested, which was 1,000 mg/kg, compared to a control group. Decreased fetal body weights and increased incomplete fetal ossification was observed at all epetraborole dose levels. The significance of these observations in humans is unknown. Based on the observed maternal and fetal adverse events in rats, epetraborole could be harmful to human fetuses when taken during pregnancy.

Amongst the patients enrolled in the first six cohorts of our Phase 1b dose-ranging study of epetraborole in healthy volunteers, the most common treatment emergent adverse events, or TEAEs, were gastrointestinal events, such as nausea, abdominal discomfort and diarrhea, and headache and vascular site access pain. Most TEAEs observed in the Phase 1b dose-ranging study were mild or moderate in severity and no severe or serious TEAEs were observed in the study. Two subjects in the study experienced TEAEs that caused premature discontinuation from epetraborole: one epetraborole subject at the 250 mg q24h dose level had mild aminotransferase increases during a concomitant upper respiratory tract infection and one epetraborole subject at the 1,000 mg q48h dose level had mild nausea. These TEAEs were both considered possibly or probably related to epetraborole. Consistent with observations in chronic toxicology studies in non-human primates and rats, dose-dependent effects on red blood cell-related hematological parameters, such as hemoglobin and reticulocytes, were observed in the Phase 1b dose-ranging study. The observed effects on hematological parameters were mild and most RBC values remained within normal limits with a slight downward trend, and the hematological parameters recovered following completion of dosing of epetraborole. No subjects discontinued therapy as a result of the hematological effects that were observed.

Additional adverse events may emerge 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. The dosing duration for administering epetraborole in humans has been limited to a maximum of 28 days in previous clinical trials, and we have initiated a pivotal Phase 2/3 clinical trial of epetraborole in patients with treatment-refractory MAC lung disease. We anticipate that the dosing duration in this pivotal Phase 2/3 clinical trial will be 16 months. The longer dosing duration expected in our pivotal Phase 2/3 clinical trial, as well as the use of epetraborole in patients with treatment-refractory MAC lung disease, may increase the potential for the emergence of new, unknown treatment-emergent adverse events. Often, it is not possible to determine whether or not a product candidate being studied caused side effects. Our current and planned clinical trials are designed to evaluate both the efficacy and safety of epetraborole. Consistent with all clinical trials, we will monitor the safety of our patients throughout our ongoing pivotal Phase 2/3 clinical trial. In addition, we plan to include an independent Safety Data Monitoring Committee (“SDMC”) to review safety as we increase dosing durations to 16 months and transition from clinical investigations in healthy volunteers to patients. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test epetraborole and our future 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, Phase 3 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 epetraborole or any future product candidate 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.

Epetraborole is being developed for use in the treatment of MAC lung disease as an add-on therapy to an optimized background regimen, which would include current standard of care drugs as outlined in the NTM treatment guidelines. Even if 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.

Moreover, if we elect, or are required, to delay, suspend, or terminate any clinical trial of any of epetraborole or any future 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 epetraborole or any of our future product candidates receive marketing 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;
- 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, similar to Arikayce;
- 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 may need to conduct a recall; 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 the continued clinical testing and potential regulatory approval of epetraborole, an element of our strategy is to discover, develop, and commercialize a portfolio of product candidates to treat rare chronic lung infections including NTM lung disease. 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 validated mechanisms. We focus our clinical development on pathogens and patients with high, unmet medical needs to leverage the development and regulatory paths available for first-in-class or best-in-class anti-infectives. 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, the PMDA, the EMA, the TGA, 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 epetraborole or our future 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 epetraborole.

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

We may not be able to initiate, continue, or complete clinical trials of epetraborole or any future 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, the PMDA, the EMA, the TGA, 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.

We may face delays and difficulties in enrollment because NTM lung disease caused by MAC is considered a rare disease (i.e., the size of the targeted patient population is small) and patients are generally managed in the outpatient setting by specialized clinics and caregivers. Patients may also be reluctant to participate in a clinical trial with an investigational drug. In addition, some of our competitors may have ongoing clinical trials to treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors. Patient enrollment is also affected by other factors including:

- 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;
- the availability 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.

Additionally, most patients with NTM lung disease have pre-existing co-morbidities, including underlying structural lung disease. Because of this, we expect difficulties in determining clinical responses in some patients in our initiated pivotal Phase 2/3 clinical trial of epetraborole, which could result in a failure to meet prespecified clinical trial endpoints. For example, even if epetraborole has a beneficial effect on culture conversion, patient-reported symptom-based outcomes may not correlate with microbiological responses.

In addition, the COVID-19 pandemic and seasonal respiratory conditions like influenza may affect the enrollment of our planned clinical trials. For example, we have experienced delays enrolling our pivotal Phase 2/3 clinical trial in part due to staff shortages and other challenges that have arisen in the wake of the COVID-19 pandemic. We truncated the sixth cohort of our Phase 1b dose-ranging study of epetraborole in Australia after a rise in COVID-19 cases in Australia resulted in recruitment challenges. Clinical trial activities, including patient enrollment and data collection, are dependent upon global clinical trial sites which have been and continue to be adversely affected by the COVID-19 pandemic. Patients may be unwilling to enroll in clinical trials due to fear of contracting COVID-19. In addition, after enrollment in our trials, patients may drop out of our trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols, due to site-related restrictions or patient quarantines after COVID-19 exposures or infections. Clinical-trial sites may experience staff shortage and personnel at clinical-trial sites may have less time to work on our trials if COVID-19 or other seasonal respiratory conditions (e.g., flu or RSV) force hospitals to prioritize resources. If patients are unable to follow the trial protocols or if our trial results are otherwise disputed due to the effects of the COVID-19 pandemic or other respiratory conditions or actions taken to mitigate spread, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for our product development.

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. Enrollment delays in these clinical trials may result in 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 publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are 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. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Risks Related to Our Dependence on Third Parties

We rely on single-sourced third parties to conduct the preclinical and nonclinical studies, clinical trials, and manufacture of our clinical trial material for epetraborole and our future product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies, trials, and manufacturing services or failing to comply with applicable regulatory requirements.

We have engaged contract research organizations, or CROs, to conduct our ongoing and planned preclinical and nonclinical studies, clinical trials and manufacture of our clinical trial material. We also expect to engage CROs for any of our other future 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, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, 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, or the ICH. We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so 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.

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, marketing approvals for epetraborole and our future 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 New Drug Application, or NDA, we submit. Any such delay or rejection could prevent us from commercializing epetraborole or any future 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 marketing approval of epetraborole or any future 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. We currently rely on third parties, such as Esteve Química, S.A. and Catalent Pharma Solutions, for drug substance and drug product manufacturing, respectively, of our current product candidate, and 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 future plans include identifying, qualifying, and contracting with a second manufacturing site to manufacture epetraborole, assuming we have adequate financial resources to pursue contingency manufacturing plans. 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 epetraborole or any of our future 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 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.

Third-party manufacturers may not be able to comply with current Good Manufacturing Practice, or cGMP, regulations or similar regulatory requirements outside the United States. 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.

Epetraborole and our future products and 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 epetraborole or any future 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 marketing approval on a timely and competitive basis.

Risks Related to the Commercialization of Epetraborole and Our Future Product Candidates

Even if epetraborole or any of our future product candidates receives marketing 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, the PMDA, the EMA, the TGA, or other comparable regulatory agencies and are able to initiate commercialization of epetraborole or any future product candidates we develop, the product candidate 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; and drugs in the target infections grow.

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, and results of operations.

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 epetraborole and other product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of NTM lung infections. Potential competitors also include academic institutions, government agencies, and other public and private research organizations. If our competitors obtain marketing approval from the FDA, the PMDA, the EMA, the TGA, 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 epetraborole or any future product candidates that we may develop, which could render our product candidate non-competitive and obsolete.

Our initial product candidate, epetraborole, is being initially developed for the treatment of patients with treatment-refractory MAC lung disease, and Insmed's Arikayce is the only currently approved therapy for the treatment of MAC lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of six consecutive months of a multidrug background regimen therapy. 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. There are a number of product candidates in clinical development by third parties that are intended to treat NTM lung disease. Some mid- to late-stage product candidates include SPR720 from Spero Therapeutics, Inc., RHB-204 from Redhill Biopharma Ltd., and omadacycline from Paratek Pharmaceuticals, Inc. In addition, there may also be unexpected or unknown competitors that we are not presently aware of.

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.

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, the PMDA, the EMA, the TGA, 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, the PMDA, the EMA, the TGA, 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 epetraborole or any future product candidates achieve marketing 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 epetaborole or our future 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 marketing 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 NTM lung infections 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 epetaborole or any future 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 epetraborole or any future 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 marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize epetraborole and any future 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 epetraborole and any future 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.

We currently hold \$5.0 million in domestic product liability insurance coverage with a per incident limit of \$5.0 million, and the required local policies for foreign clinical trials, which 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 epetaborole or any future product candidates internationally, which could affect our business.

We may seek regulatory approval for epetaborole or other future 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, or 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.

As of December 31, 2022, we had 32 employees and one part-time employee. We are highly dependent on the management, research and development, clinical, financial, and business development expertise of Eric Easom, our co-founder, president, and chief executive officer, Paul Eckburg, M.D., our chief medical officer, Sanjay Chanda, Ph.D., our chief development officer, Lucy Day, our chief financial officer, Josh Eizen, J.D., our chief legal officer, Kevin Krause, our chief strategy officer, and Michael R.K. (Dickon) Alley, Ph.D., our co-founder and head of biology, 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 epetaborole or any future 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.

Our business could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic.

Our business could be adversely affected by health epidemics, including the COVID-19 pandemic and influenza, in regions where we or third parties on which we rely have manufacturing facilities, concentrations of potential clinical trial sites or other business operations. For example, as a result of the COVID-19 pandemic, the State of California, where our operations are located, has from time to time issued orders limiting activities to varying levels, including at the most restrictive level, an order for all residents to remain at home, except for the performance of essential activities, which include biomedical research. We have implemented policies that enable our employees to work remotely, and such policies may continue for an indefinite period. In accordance with state and local mandates, from time to time, we have also implemented various safety protocols for all on-site personnel, including the requirements to wear masks, suspend all non-essential travel for our employees and maintain social distance. We continue to evaluate our protocols and practices as the global response to the COVID-19 pandemic continues to evolve. There can be no assurance that we will be able to avoid part or all of any impact from the spread of COVID-19 or its consequences.

In addition, our current preclinical and nonclinical studies and current and future clinical trial plans may be affected by the COVID-19 pandemic or other epidemic. Site initiation and patient enrollment may be delayed due to potential and ongoing patients being exposed to COVID-19, staff shortages and prioritization of hospital resources toward the COVID-19 pandemic or other epidemic, which may delay enrollment in our current and future global clinical trials, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Further, some of our suppliers may experience disruption to their respective supply chain due to the effects of health epidemics, including the COVID-19 pandemic, which could delay, prevent, or impair our development or commercialization efforts.

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. Several measures are currently being implemented by the United States and other governments to address the current COVID-19 pandemic and its economic impacts. At this time, it is impossible to predict the impact of these measures and whether or not they will have unforeseen negative consequences for our business. We do not yet know the full extent of potential delays or impacts on our business, our planned preclinical studies or clinical trials, healthcare systems or the global economy as a whole; nor do we know when and how such regulations may be eased. The foregoing and other continued disruptions to our business as a result of COVID-19 could result in an adverse effect on our business, results of operations, financial condition and cash flows. Furthermore, the COVID-19 pandemic could heighten the risks in certain of the other risk factors described herein.

Macroeconomic uncertainties and the COVID-19 pandemic have in the past and may continue to adversely impact our business, results of operations and financial condition.

There is currently an uncertain and inflationary economic environment in the United States, partially as a result of the COVID-19 pandemic and efforts to contain it and manage its impacts, which have created significant macroeconomic disruption and volatility. 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. For example, the Federal Reserve recently raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. For example, the Company has a banking relationship with Silicon Valley Bank ("SVB"). On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. On March 12, 2023, the Federal Reserve Board approved actions enabling the FDIC to complete its resolution of SVB in a manner that fully protects all depositors. Based on the foregoing and the Company's analysis of the components of its relationship with SVB, the Company does not expect these events to have a material impact on the Company's financial statements. Similarly, the ongoing military conflict between Russia and Ukraine has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions 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, 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 and the COVID-19 pandemic continue to harm our business, results of operations and financial condition, many of the other risks described in this "Risk Factors" section will be exacerbated.

Our cash and cash equivalents may be exposed to failure of our banking institutions.

While we seek to minimize our exposure to third-party losses of our cash and cash equivalents, we hold our balances in a number of large financial institutions. Notwithstanding, those institutions are subject to risk of failure. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was unable to continue their operations and the Federal Deposit Insurance Corporation was appointed as receiver for SVB and created the National Bank of Santa Clara to hold the deposits of SVB after SVB was unable to continue their operations. As of March 29, 2023, we did not hold material cash and cash equivalents with SVB. Majority of our cash and cash equivalents are held with other large financial institutions, and we do not expect further developments with SVB to have a material impact on our cash and cash equivalents balance, expected results of operations, or financial performance for the foreseeable future. However, if further failures in financial institutions occur where we hold deposits, we could experience additional risk. Any such loss or limitation on our cash and cash equivalents would adversely affect our business.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail 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.

The above material weaknesses resulted in adjustments to the redeemable convertible preferred stock, tranche liability and accrued expenses balances, which were recorded prior to the issuance of the financial statements, as of and for the years ended December 31, 2020 and 2021. 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, or 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.

To address our material weaknesses, we are implementing measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to the material weaknesses. These measures include (i) the ongoing hiring of additional accounting personnel; (ii) the design and implementation of our financial control environment, including the establishment of formal accounting policies and procedures, financial reporting controls and controls to account for and disclose complex transactions; and (iii) implementation of an upgraded accounting system with IT controls to insure appropriate and restricted access to our accounting applications, programs, and data.

We are working to remediate the material weaknesses as efficiently and effectively as possible and expect full remediation could potentially go beyond December 31, 2023. We cannot assure you that there will not be future material weaknesses in our internal control over financial reporting in the future. Any 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. If we fail to remediate our identified material weaknesses, or identify additional material weaknesses, in our internal control over financial reporting investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq Stock Market LLC, the Securities and Exchange Commission, or SEC, or other regulatory authorities. Failure to remedy any material weakness 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.

We expect to expand our research, development, and business capabilities and potentially implement sales, marketing, and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As the clinical development of epetraborole and any of our future product candidates progresses, we also expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if epetraborole or any future product candidate receives marketing approval, sales, marketing, and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to 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 anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may 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.

From time to time, we may 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;
- 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.

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 epetraborole or our future 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.

We do not own any issued patents and we in-license patents and patent applications for epetraborole, our lead drug compound, and 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 epetraborole and any of our future product candidates. We seek to protect our proprietary position by 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, or 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 epetraborole or our future 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, or 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, 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 loss of exclusivity or freedom to operate or 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 prospects.

Our rights to develop and commercialize our technology, epetraborole, and our other future 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.

We are heavily reliant upon licenses to certain patent rights and other intellectual property that are important or necessary to the development of epetraborole or our future 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 Bria Biosciences.

Anacor has relied upon, and any future licensors may have relied 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 epetraborole or our other future 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 epetraborole, and development of any future product candidates may, require us to enter into additional license or collaboration agreements. For example, our licensors or other third parties may develop intellectual property covering epetraborole which we have not licensed. 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 epetraborole or our future product candidates in the future.

Our license agreement with Anacor, and other intellectual property-related agreements we may enter into in the future 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 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 or any 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 prospects.

Under our license agreement with Anacor, and any 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 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 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, to identify and develop product candidates. We may find it necessary or prudent to obtain licenses from such 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 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 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 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 we may own. To counter such infringement, misappropriation, 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. 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, or PGR, inter partes review, or 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 epetaborole or our other future 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 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 in-licensed patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our in-licensed patents could limit our ability to assert our 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 epetaborole and any of our other future product candidates that are approved for marketing, and if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the 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 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, 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 prospects.

Competitors or other third parties may infringe, misappropriate or otherwise violate our in-licensed issued patents or other intellectual property we may own. To counter such infringement, misappropriation, 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. 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, or PGR, inter partes review, or 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 epetraborole or our other future 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 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 in-licensed patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our in-licensed patents could limit our ability to assert our 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 epetraborole and any of our other future product candidates that are approved for marketing, and if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the 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 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, 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 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 epetraborole or other future product candidates and use our proprietary chemistry technology without infringing, misappropriating or otherwise violating the intellectual property 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 epetraborole or other future 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 or violate such third party's intellectual property. 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, 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 epetraborole or other future 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 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 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 prospects.

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

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 to execute agreements assigning such intellectual property 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 rights 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 epetraborole or other future 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 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 epetraborole or any future 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 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 epetraborole or other future product candidates could be adversely affected and our business and competitive position would be harmed.

In addition to seeking patent protection for epetraborole or other future 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 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 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 marketing 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, or 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 term of any such 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 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 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 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 prospects.

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

Filing, prosecuting, 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.

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 epetraborole, our future 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 in-licensed patents, 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 in-licensed patents at risk of being invalidated or interpreted narrowly and our 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 prospects may be adversely affected.

Risks Related to Regulatory Approval of Epetraborole and Our Future 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 epetraborole or our future product candidates, and our ability to generate revenue will be materially impaired.

Epetraborole and our future 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, 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 marketing 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. We as a company only have limited experience in filing and supporting the applications necessary to gain marketing approvals and may rely on third-party contract research organizations to assist us in this process.

The time required to obtain approval, if any, by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities, government budget, and funding levels and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years, and disruptions at the FDA and other agencies may slow the time necessary for new drugs to be reviewed and/or approved. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough nonessential employees and stop routine activities. Events like this could significantly impact the ability of the FDA to timely review and process our regulatory submissions.

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, recent changes to leadership, enhanced focus on countermeasures related to the COVID-19 pandemic, 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. For instance, we met with the PMDA and gained alignment on the use of a microbiological primary endpoint to support registration in Japan. We are planning to include Japanese patients in the pivotal Phase 2/3 clinical trial and expect that the data from the ongoing pivotal Phase 2/3 clinical trial of oral epetraborole for treatment-refractory MAC lung disease, if positive, will serve as the basis for the application for marketing approval in Japan. We have not obtained regulatory approval for any product candidate, and it is possible that epetraborole and any product candidates we may seek to develop in the future will never obtain regulatory approval. We are not permitted to market any product candidate in the United States until we receive regulatory approval of an NDA from the FDA.

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.

We have not submitted a marketing application for epetraborole or any other product candidates in any country or region. Any marketing application must include extensive preclinical, nonclinical, and clinical data and supporting information to establish the product candidate's safety and efficacy for each desired indication. The marketing application(s) must also include significant information regarding the chemistry, manufacturing, and controls for the product candidate. Obtaining marketing authorization is a lengthy, expensive, and uncertain process. The FDA, EMA, PMDA, TGA, and other comparable regulatory authorities have substantial discretion in the review and approval process and may refuse to accept for filing any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical, or other studies. Foreign regulatory authorities have differing requirements for approval of drugs with which we must comply prior to marketing. There can be no assurance that any foreign regulatory authorities will accept FDA approval as sufficient to support approval in that country. Obtaining marketing approval for marketing of a product candidate in one country does not ensure that we will be able to obtain marketing approval in other countries, but the failure to obtain marketing approval in one jurisdiction could negatively affect our ability to obtain marketing approval in other jurisdictions. The FDA or any foreign regulatory bodies can delay, limit or deny approval of epetraborole or other future product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including:

- disagreement with the design 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 (for example, otherwise positive epetraborole results may be called into question if patient reported outcomes introduce ambiguity due to factors such as co-morbidities and other underlying patient issues);
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- 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; 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 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.

Future legislation, and/or regulations and policies adopted by the FDA, the PMDA, the EMA, the TGA, or comparable regulatory authorities, may increase the time and cost required for us to conduct and complete clinical trials of epetraborole or other future product candidates.

The FDA has established regulations to govern the drug development and approval process, as have foreign regulatory authorities. The policies of the FDA and other regulatory authorities may change and additional laws may be enacted or government regulations may be promulgated that could prevent, limit, delay, or alternatively accelerate regulatory review of epetraborole or other future product candidates. Further, disruptions at the FDA and other agencies may prolong the time necessary for new drugs 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 employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We have received orphan drug designation for epetraborole in the United States and in Europe, and we may seek orphan drug designation for epetraborole in other regions or indications, or for our future product candidates. 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 sought and have received orphan drug designation from the FDA and orphan medicinal product designation from the European Commission for epetraborole for the treatment of infections caused by NTM; however, we may not be able to maintain this status. There can be no assurance that the FDA or European Commission will grant orphan drug designation for epetraborole to treat any other condition for which we may apply. We may also seek orphan drug designation for future product candidates, and we may be unsuccessful in obtaining this designation.

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 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 indication 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.

Pediatric exclusivity can provide an additional six months of market exclusivity in the United States. In addition, more than one product may be approved by the FDA for the same orphan indication or disease, as long as the products are different drugs. As a result, even though we have obtained orphan drug designation from the FDA for epetraborole for the treatment of infections caused by NTM, if epetraborole is approved by the FDA and receives orphan drug exclusivity, the FDA can still approve other drugs for use in treating the same indication or disease covered by epetraborole, which could create a more competitive market for us. The failure to successfully obtain orphan drug market exclusivity or pediatric drug market 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 condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same 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. While we have obtained orphan drug designation for epetraborole for the treatment of infections caused by NTM, we may not be able to maintain such designation; and while we may seek orphan drug designations for epetraborole for other indications or for any future product candidates for applicable indications, we may never receive such designations. Even though we have received orphan drug designation for epetraborole for the treatment of infections caused by NTM, and may receive further such designations in the future, there is no guarantee that we will utilize the benefits of those designations.

We have received FDA Qualified Infectious Disease Product, or QIDP, designation for epetraborole, and may seek designation of any future candidates as QIDPs. Even if we receive such designations, there is no assurance that the FDA will approve a product candidate.

A QIDP is an antibacterial or antifungal drug intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or certain “qualifying pathogens.” Upon the regulatory approval of an NDA for a drug product designated by the FDA as a QIDP, the product is granted an additional period of five years of regulatory exclusivity. Even though we have received a QIDP designation for epetraborole, or may receive such designation for any future product candidate, there is no assurance that such product candidate will be approved by the FDA.

We have received Fast Track designation from the FDA, but receipt of such designation may not actually lead to a faster development, regulatory review, or approval process, and does not assure ultimate FDA approval.

We received Fast Track designation from the FDA to investigate epetraborole for treatment-refractory MAC lung disease. We may seek breakthrough therapy designation for this indication, or Fast Track designation for future product candidates or for other indications.

A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA can also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review, or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification and rescind the breakthrough designation.

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even though we have received Fast Track designation to develop epetraborole in certain indications, or if we receive Fast Track designation for other product candidates or indications, we may not experience a faster development process, review, or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may seek FDA approval using the limited-population antibacterial drug, or LPAD, pathway. We may not be able to obtain or maintain LPAD designations for epetraborole and/or any future candidates, and we may be unable to take advantage of the benefits associated with LPAD designation.

We may seek FDA approval for epetraborole using the LPAD pathway, through which the FDA may review and approve new antibacterial drugs to treat serious bacterial diseases in patients with an unmet medical need and for which effective antibacterial drugs are limited or lacking. This pathway may allow us to conduct a more streamlined development program. In accordance with the 2017 FDA Guidance for Industry Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases, any drug approved under this pathway must be labeled with the statement “Limited Population” in a prominent manner and adjacent to the proprietary name of the drug and the INDICATIONS AND USAGE section of the label pathway should summarize the limitations of available data that supported the approval. For example, but not limited to, the label must specify the limitations of the pathogens evaluated in the clinical trial or clinical trials conducted to evaluate the approved drug or the limitations of the amount of available safety data.

If we do not receive LPAD pathway approval (for example, because the FDA determines the trial does not meet the requirement of safety and efficacy necessary for approval), longer and more costly clinical trials may be required. The FDA does not determine if the LPAD pathway is applicable until the time of the NDA submission, and this creates uncertainty as to our ability to use this pathway.

We may seek accelerated approval in the United States for our epetraborole and future 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 marketing 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. Prior to seeking such accelerated approval we will continue to seek feedback from the FDA or comparable foreign regulatory agencies and otherwise evaluate our, or their, ability to seek and receive such accelerated approval.

There can be no assurance that the FDA or foreign regulatory agencies will agree with our surrogate endpoints or intermediate clinical endpoints in any of our clinical trials, or that we will decide to pursue or submit any additional NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval. Furthermore, for any submission of an application for accelerated approval or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all.

In December 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act ("FDORA"), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period until commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Under accelerated or conditional approval regulations of the FDA or comparable foreign regulatory authorities, we must comply with post-approval development and regulatory requirements to maintain the approval and we fail to do so, the FDA or comparable foreign regulatory authorities could withdraw an approval for the indication that received accelerated or conditional approval, which would lead to substantially lower revenues.

For drugs approved under the FDA's Accelerated Approval Program, the FDA typically requires post-marketing confirmatory trials to confirm the anticipated clinical benefit. These confirmatory trials must be completed with due diligence. If we were to fail to perform the required post-approval studies with due diligence or on a timely basis, the FDA has the authority to withdraw approval of a drug following a hearing conducted under the FDA's regulations, which could have a material adverse impact on our business. We cannot be certain of the results of any confirmatory clinical studies or what action the FDA may take if the results of those studies are not sufficient for full approval.

Failure to obtain marketing approval in foreign jurisdictions would prevent epetraborole or our future 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 our product candidates in foreign jurisdictions.

In order to market and sell epetraborole or our future product candidates in Japan, the European Union, United Kingdom, other areas of Asia, and any other jurisdictions, we must obtain separate marketing 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 marketing approvals for epetraborole or any future 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 marketing approval of epetraborole or any future product candidates is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including the potential requirements to implement a risk evaluation and mitigation strategy or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. 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 marketing 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, including manufacturing, production, product surveillance, and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our product candidates withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with epetraborole or any future product candidates, when and if any of them are approved.

The FDA and other federal and state agencies, including the U.S. Department of Justice, or the DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market epetraborole or our future product candidates for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws.

- Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:
- litigation involving patients taking our product candidates;
- restrictions on such products, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;

- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

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, the PMDA, the EMA, 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 September 2022 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 epetraborole or one of our future 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, and results of operations.

If we participate in the Medicaid Drug Rebate Program, 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, health information privacy and security, 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 marketing 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, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, 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 marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation 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, order, or recommendation 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;
- 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 or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or 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, created under Section 6002 of Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and its implementing regulations, created annual reporting requirements for manufacturers of drugs, devices, biologicals, and medical supplies for certain 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; state and local laws requiring the licensure of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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 epetaborole or our future 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, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. 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 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 will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. Additionally, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. 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 epetaborole or our future product candidates or additional pricing pressures.

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 sensitive information, including confidential business information and information related to our employees and we expect to maintain 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, 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, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure, and protection of health-related and other personal information. 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 and regulations 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 the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition, results of operations or prospects. Any failure by us or our third-party processors to comply with these data protection and privacy laws and regulations 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 of remediation, and adverse publicity, any of which could negatively affect our operating results and business. 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. 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 prospects may be adversely affected.

Our product candidates may be subject to government price controls that may affect our revenue.

There has been heightened governmental scrutiny in the United States and abroad of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the state level, legislatures have become increasingly aggressive 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 and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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 marketing 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 epetraborole or our future 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.

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 epetraborole or our future 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.

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 ("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 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 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 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, or 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.

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, results of operations, financial condition, and 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 eptetraborole and planned pipeline and expansion 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, 2022, we had federal and state net operating loss, or NOLs, carryforwards of approximately \$43.2 million and \$66.3 million, respectively. Under the Tax Cuts and Jobs Act of 2017, or the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or 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. It is uncertain if and to what extent various states will conform 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, or 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 may be volatile.

The trading price of our common stock is likely to be highly volatile and could be 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 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 eptaborole or any future 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, Japan or other countries where we conduct critical business (including those relating to macroeconomic events, such as the COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine, any global economic slowdown or recession, rising inflation, and increased interest rates);
- 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 Stock Market LLC, 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 devotes 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 information technology systems or data security 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 sensitive information, including intellectual property, proprietary business information, personal 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 sensitive information. We have also outsourced elements of our operations, including elements of our information technology infrastructure, to third parties and, as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential 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 sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal, and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature 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. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our or our third-party vendors’ or business partners’ information technology systems or other similar data security 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, sensitive information, which could result in financial, legal, regulatory, business, and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war, and telecommunication and electrical failures, 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 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 that cause loss, destruction, unavailability, alteration, dissemination of, or damage, or unauthorized access to, our data, including personal data, assets, and other data processed or maintained on our behalf, that could have a material adverse effect upon our reputation, business, operations, or financial condition.

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 security incidents. There is no way of knowing with certainty whether we have experienced any data security 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 they have been attacked. Any event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and state breach notification laws and foreign law equivalents, subject us to time-consuming, distracting, and expensive litigation, 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. This could result in increased costs to us, 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 security incidents or other inappropriate access events, 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, data security 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. Any of the foregoing could have a material adverse effect on our reputation, business, operations, or financial condition.

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 Form 10-K. In particular, in this Form 10-K, we have provided only two comparative periods of unaudited financial statements and we have not included 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.”

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. On December 22, 2017, President Trump signed into law the Tax Act, which significantly revised the Code. The overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. 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 have operations 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 and financial condition. 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 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 2023. We leased approximately 2,500 additional square feet of adjacent office space pursuant to a lease agreement that commenced in September 2021 and expires in August 2023. Both leases contain two additional 12-month renewal options through August 2025.

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 8—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, 2023, we had 39 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 holders of record also does not include stockholders whose shares may be held in trust by other entities.

Unregistered Sales of 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 initial public offering (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 planned 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, 2022 and results of operations for the years ended December 31, 2022 and 2021 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 2022 and 2021 items and year-to-year comparisons between 2022 and 2021. 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 II, Item 1A of this Form 10-K. See also the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company developing treatments for rare, chronic, and serious infectious diseases with high unmet needs. Our initial product candidate is epetraborole, a once-daily, oral treatment for patients with non-tuberculous mycobacterial ("NTM") lung disease, a rare, chronic and progressive infectious disease caused by bacteria known as mycobacteria that leads to irreversible lung damage and can be fatal. Epetraborole has 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 have initiated patient enrollment in a pivotal Phase 2/3 clinical trial in treatment-refractory mycobacterium avium complex ("MAC") lung disease, which is the most common type of NTM lung disease. The Company expects to complete enrollment in the Phase 2 portion of the pivotal Phase 2/3 clinical trial in mid-2023 and plans to seamlessly begin enrollment of the Phase 3 portion of the trial immediately thereafter. We expect to announce top-line data for each of the Phase 2 and Phase 3 portions of the trial approximately nine months after the completion of enrollment in each respective portion of the trial. We've selected a 500 mg once-daily dose for our pivotal Phase 2/3 clinical trial in treatment-refractory MAC lung disease patients based on data from our completed Phase 1b dose-ranging study of epetraborole administered orally for 28 days in healthy volunteers in Australia (EBO-101), the completed Phase 1 safety and pharmacokinetic study in healthy volunteers in Japan (EBO-103), and data from our two nonclinical chronic toxicology studies (six-month rats and nine-month non-human primates). Based on feedback from the U.S. Food and Drug Administration ("FDA") and Japan's Pharmaceuticals and Medical Devices Agency ("PMDA"), we believe our pivotal Phase 2/3 clinical trial design has the potential to be sufficient for regulatory approval in the United States and Japan and potentially other territories. We received Fast Track designation by the FDA to investigate epetraborole for treatment-refractory MAC lung disease. Epetraborole has also been designated as a Qualified Infectious Disease Product ("QIDP") for treatment-refractory MAC lung disease by the FDA and has received orphan drug designation from the FDA and orphan medicinal product designation from the European Commission for the treatment of NTM lung disease. We met with the PMDA and gained alignment on the use of a microbiological primary endpoint to support registration in Japan. We recently completed a Phase 1 safety and pharmacokinetics study of oral epetraborole in healthy volunteers in Japan (EBO-103), which confirmed the appropriateness of the 500 mg once-a-day oral dose for Japanese subjects and subjects with different ADH1B genotypes, and are planning to include Japanese patients in the pivotal Phase 2/3 clinical trial. We expect that the data from the ongoing pivotal Phase 2/3 clinical trial of oral epetraborole for treatment-refractory MAC lung disease, if positive, will serve as the basis for the application for marketing approval in Japan. NTM prevalence in Japan is the highest in the world and is considered a high unmet need as well as a major market opportunity for 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 has the potential to become an important component of a multi-drug treatment regimen for patients suffering from NTM lung disease.

Since launching operations in November 2019, we have devoted substantially all of our resources to developing our initial product candidate. 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; and hire additional personnel. In addition, we expect to incur additional 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 \$41.0 million and \$21.5 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of \$89.7 million. We have funded our operations from the sale and issuance of redeemable convertible preferred stock and proceeds from our initial public offering ("IPO"). 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.

As of December 31, 2022, we had cash, cash equivalents and short-term investments of \$96.1 million. We believe that our available cash will be sufficient to fund our planned operations for at least 12 months following the date of issuance 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 epebraborole is approved for the treatment of NTM lung disease, we intend to hire and deploy a specialty sales force, which will increase our operating costs.

We are continuing to monitor the impact of the evolving effects of the COVID-19 pandemic on our ability to develop our product candidates. The evolving effects of the COVID-19 pandemic appear to have negatively affected enrollment at our clinical sites. Some of the sites participating in our clinical trials are affected by reduced capacity, staffing shortages, or other effects of the COVID-19 pandemic. At some sites, we are experiencing impacts to our ability to activate sites, screen and enroll patients. The extent of the impact on our clinical trials depends on the current stage of activities at a given site, for example study start up versus post-enrollment, and the number of impacted sites participating in that trial. Impacts on diagnosis rates associated with the COVID-19 pandemic may also negatively impact enrollment. There may continue to be adverse impacts to our clinical study timelines, which, depending upon the duration and severity of the evolving effects of the COVID-19 pandemic, could ultimately delay data availability.

The extent to which the evolving effects of the COVID-19 pandemic (or any future pandemic) impact our business will depend on future developments that are highly uncertain, such as virus variants that may prove to be especially contagious or virulent, the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the United States and in other countries, business closures or business disruptions and the effectiveness of actions taken to contain and treat the disease. For more information on the risks and uncertainties associated with the evolving effects of the COVID-19 pandemic on our business and our clinical development and regulatory efforts, see "Part II Item 1A—Risk Factors." As we resume more travel and in-person interactions after pauses earlier in the pandemic, we may subsequently decide or be forced to resume a more restrictive remote work model, whether as a result of further spikes or surges in COVID-19 infection or hospitalization rates, COVID-19 variants, government actions, restrictions at healthcare institutions, or otherwise. Future COVID-19 related restrictions could negatively impact research and development activities.

Additionally, other recent macroeconomic events including elevated inflation, the U.S. Federal Reserve raising interest rates, supply chain disruptions, labor shortages, fluctuations in currency exchange rates, and the Russian invasion of Ukraine, have led to further economic uncertainty.

Because of the above and 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.

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. 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. Costs are not tracked on a project-by-project basis, because substantially all of our research and development resources to date are focused primarily on our lead drug product candidate, epetraborole.

We expect our research and development expenses to increase substantially in the future, as we advance epetraborole and any future products into and through additional 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 as we increase our headcount, expand our operating activities, prepare for potential commercialization of our current and future product candidates, and support our operations as a public company, including increased expenses related to legal, accounting, regulatory, and tax-related services associated with maintaining compliance with requirements of Nasdaq Stock Market LLC and the SEC, directors and officers liability insurance premiums and investor relations activities.

Interest Income

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

Other Expense

Other expense consists of expense associated with foreign currency fluctuations.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

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

	Year Ended December 31,			
	2022	2021	Change	% Change
	(in thousands, except percentages)			
Operating Expenses:				
Research and development	\$ 28,511	\$ 16,156	\$ 12,355	76%
Research and development—related party	1,000	750	250	33%
General and administrative	12,751	4,668	8,083	173%
Total operating expenses	42,262	21,574	20,688	96%
Loss from operations	(42,262)	(21,574)	(20,688)	96%
Interest income	1,351	69	1,282	*
Other income (expense)	(45)	(38)	(7)	18%
Net loss	\$ (40,956)	\$ (21,543)	\$ (19,413)	90%

*Change not meaningful

Research and Development Expenses

Research and development expenses, including related-party research and development expenses, were \$29.5 million for the year ended December 31, 2022 compared to \$16.9 million for the year ended December 31, 2021. The increase of \$12.6 million was primarily due to increases in related-party license fees, personnel-related expenses, clinical trial costs and outside services and consultants expenses, partially offset by lower outside research and toxicology study costs. Related-party license fees increased by \$0.3 million as a result of the milestone payment to Anacor made related to the enrollment of our first patient in our pivotal Phase 2/3 clinical trial. Personnel-related costs increased by \$4.5 million, as a direct result of our increased research and development headcount. Costs related to clinical trials and services increased by \$5.5 million and costs related to chemistry manufacturing and controls activities increased by \$0.7 million, offset by a decrease in research study costs of \$0.5 million. Outside services and consultants increased by \$1.9 million for clinical trial activities, preclinical testing, regulatory and manufacturing costs. Other expenses, including rent, utilities and information technology expenses, increased by \$0.2 million to support our increased headcount.

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

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Clinical trials	\$ 9,563	\$ 4,031	\$ 5,532
Chemistry manufacturing and controls expenses	3,749	3,061	688
Research and preclinical studies	3,368	3,867	(499)
Research and development—related party	1,000	750	250
Other expenses	656	419	237
Personnel related expenses	8,266	3,761	4,505
Consulting and outside services	2,909	1,017	1,892
Total research and development expenses	\$ 29,511	\$ 16,906	\$ 12,605

General and Administrative Expenses

General and administrative expenses were \$12.8 million for the year ended December 31, 2022 compared to \$4.7 million for the year ended December 31, 2021. The increase of \$8.1 million was primarily attributable to a \$3.7 million increase in personnel-related costs as we expanded our headcount, a \$2.0 million increase in insurance and other expenses, a \$0.9 million increase in consulting and outside services, and a \$1.0 million increase in professional services expenses to support our ongoing operations as a public company. Other expenses, including rent, utilities and information technology expenses, increased by \$0.5 million to support our increased headcount.

Liquidity and Capital Resources

Sources of Liquidity

From our inception through December 31, 2022, we have funded our operations through our IPO and private placements of our redeemable convertible preferred stock and have raised net cash proceeds of \$70.4 million and \$91.6 million from our IPO (including the exercise of the underwriter's overallotment option) and the issuance of our redeemable convertible preferred stock, respectively. Key financing milestones include the following:

In November 2019, we raised net cash proceeds of \$8.1 million from issuance of our Series A redeemable convertible preferred stock.

In January and March 2020, we raised net cash proceeds of \$0.2 million from issuance of our Series A redeemable convertible preferred stock.

In October 2020, we raised net cash proceeds of \$3.6 million from additional issuances of our Series A redeemable convertible preferred stock.

In March 2021, we raised net cash proceeds of \$79.7 million from issuance of our Series B redeemable convertible preferred stock.

In March 2022, we raised net cash proceeds of \$60.9 million from our IPO.

In April 2022, we raised net cash proceeds of \$9.5 million from the exercise of the underwriter's option to purchase additional shares.

Future Funding Requirements

We have incurred net losses since our inception. For the years ended December 31, 2022 and 2021, we had net losses of \$41.0 million and \$21.5 million, respectively, and we expect to incur substantial additional losses in future periods. As of December 31, 2022, we had an accumulated deficit of \$89.7 million. As of December 31, 2022, we had cash, cash equivalents and investments of \$99.3 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 issuance of this Form 10-K.

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 lead drug product candidate, epetraborole, including conducting ongoing preclinical and nonclinical studies, clinical trials, clinical trial 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 epetraborole and any future 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 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 our current and any future clinical trials, including our pivotal Phase 2/3 clinical trial of epetraborole;
- 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 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 our current and 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 of this Form 10-K titled “Risk Factors” 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,	
	2022	2021
	(in thousands)	
Cash used in operating activities	\$ (33,462)	\$ (20,484)
Cash used in investing activities	(21,771)	(50,024)
Cash provided by financing activities	70,355	78,535
Net increase in cash	<u>\$ 15,122</u>	<u>\$ 8,027</u>

Cash Used in Operating Activities

Net cash used in operating activities was \$33.5 million for the year ended December 31, 2022, which consisted of a net loss of \$41.0 million, due to the use of funds to develop our initial drug product candidate offset by a net increase of \$3.7 million in our net operating assets and liabilities and \$3.8 million in non-cash charges. The net increase in our operating assets and liabilities was primarily due to an increase of \$5.5 million in accounts payable, accrued compensation and accrued liabilities due to an increase in accrued research and development expenses, partially offset by an increase of \$1.7 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 \$4.4 million and non-cash operating lease expense of \$0.1 million, partially offset by net accretion of discounts on investments of \$0.7 million.

Net cash used in operating activities was \$20.5 million for the year ended December 31, 2021, which consisted of a net loss of \$21.5 million, due to the use of funds to develop our initial drug product candidate and an increase in prepaid expenses and other current assets of \$1.4 million, partially offset by non-cash stock-based compensation expense of \$1.0 million and an increase in accounts payable, accrued compensation and accrued liabilities of \$1.4 million due to an increase in accrued research and development expenses.

Cash Used in Investing Activities

Net cash used in investing activities was \$21.8 million for the year ended December 31, 2022, which primarily consisted of \$93.8 million in purchases of investments, partially offset by \$72.0 million in proceeds from maturities of investments.

Net cash used in investing activities was \$50.0 million for the year ended December 31, 2021, which primarily consisted of \$77.3 million in purchases of investments offset by \$27.3 million in proceeds from the maturity of investments.

Cash Provided by Financing Activities

Net cash provided by financing activities was \$70.4 million for the year ended December 31, 2022, which primarily consisted of net proceeds from issuance of common stock in our IPO.

Net cash provided by financing activities was \$78.5 million for the year ended December 31, 2021, which consisted of net proceeds from the closing of our Series B redeemable convertible preferred stock of \$79.7 million, offset by payment of deferred offering costs in conjunction with our IPO of \$1.2 million.

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 and clinical trial materials, 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, or 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 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: estimating the 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 10—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, 2022 and 2021. 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, 2022 and 2021, there was no cash received and an insignificant amount of cash received upon exercise of stock options, respectively.

Common Stock Valuations

Prior to our IPO, in the absence of a public trading market for our common stock, the estimated fair value of the common stock underlying our stock options was determined at each grant date by our Board, with input from management. All options to purchase shares of our common stock are intended to be exercisable at a price per share not less than the per-share fair value of our common stock underlying those options on the date of grant.

On each grant date, we developed an estimate of the fair value of our common stock based on the information known to us on the date of grant, upon a review of any recent events and their potential impact on the estimated fair value per share of the common stock, and valuations from an independent third-party valuation firm.

The valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid.

The assumptions used to determine the estimated fair value of our common stock are based on numerous objective and subjective factors, combined with management judgment, including:

- external market conditions affecting the pharmaceutical and biotechnology industry and trends within the industry;
- our stage of development and business strategy;
- the rights, preferences and privileges of our redeemable convertible preferred stock relative to those of our common stock;
- the prices at which we sold shares of our redeemable convertible preferred stock;
- our financial condition and operating results, including our levels of available capital resources;
- equity market conditions affecting comparable public companies; and
- general U.S. market conditions and the lack of marketability of our common stock.

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, we considered the following methods:

- **Option Pricing Method.** Under the option pricing method, or OPM method, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- **Current Value Method.** Under the current value method, or CVM method, the Company's current value is allocated among various equity holders based on liquidation preferences and other rights under the assumption that all capital owners act to maximize their financial return.
- **Probability-Weighted Expected Return Method.** The probability-weighted expected return method, or PWERM method, is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.
- **Hybrid Method.** Under the Hybrid Method the Company's current value is estimated based on a combination of the OPM, PWERM, and CVM methods, whereby each valuation method is applied to a different scenario. The different scenarios are then weighted based on their probable outcomes.

As we had recent arms-length financing transactions of our Series A and Series B redeemable convertible preferred stock, we determined that the subject company transaction method under the market approach was the most appropriate method for determining enterprise value through December 31, 2021. The subject company transaction method consists of examining prior arms-length transactions of the subject company and implies a total value of the enterprise based on the price paid in the recent transaction. In using the subject company transaction method, we took into account the total consideration paid for the most recent round of financing and the rights and preferences of the stockholders of the various classes of equity outstanding. In addition, the method for inferring the equity value implied by a recent financing transaction involved making assumptions for the expected time to liquidity, volatility, and risk-free rate.

Through December 31, 2021, based on our early stage of development and other relevant factors, we determined that the OPM method was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock.

Subsequent to December 31, 2021 and through March 23, 2022, prior to the availability of a market price for our common stock on the Nasdaq Global Select Market, we used the Hybrid Method to determine our enterprise value. We took into account our estimated equity value of our anticipated IPO, the estimated present value of the assumed IPO price per share, the estimated time to IPO and a discount for lack of marketability. We also factored in the non-IPO Scenario, assumed that we will stay private and used a hybrid backsolve method to conclude our equity value based on our most recent arms-length financing transaction, adjusted for market trends. The non-IPO Scenario also involved making assumptions for the expected time to liquidity, volatility, and risk-free rate.

Subsequent to December 31, 2021 and through March 23, 2022, we determined that the Hybrid Method was also the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock. The OPM and CVM methods were used based on the future IPO Scenario, equity value and the expected future allocation to the preferred and common stockholders. The CVM and OPM methods were combined and weighted to reflect our estimation of the occurrence of each scenario.

In determining the estimated fair value of our common stock, our Board also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of our common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

There are significant judgments and estimates inherent in the determination of our enterprise value and the fair value of our common stock, such as those regarding our discount rates, the selection of comparable companies, and the probability of possible future events. Such estimates involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different. Changes in judgements could have a material impact on our results of operation. Following the completion of the IPO, the fair value of our common stock is based on the closing quoted market price of our common stock on the date of grant.

On March 24, 2022, the SEC declared effective the registration statement on Form S-1 (File No. 333-263295) relating to the registration of common stock issued in our IPO. All subsequent grants of equity following the IPO will be made at the closing price on the Nasdaq Global Select Market on the date of grant under the symbol "ANTX."

Redeemable Convertible Preferred Stock

We recorded all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The redeemable convertible preferred stock was recorded outside of permanent equity because while it is not mandatorily redeemable, in certain events considered not solely within our control, such as a merger, acquisition, or sale of all or substantially all of our assets (each, a deemed liquidation event), the redeemable convertible preferred stock would have become redeemable at the option of the holders of at least a majority of the then outstanding shares. In addition, shares of preferred stock must be redeemed by the Company at a price of \$2.55 and \$15.00 per share for Series A and Series B redeemable convertible stock, respectively, plus any accrued dividends (whether or not declared) in three annual installments on or after the seventh anniversary of the Series B original issue date (on or after March 5, 2028) upon a written request by at least two-thirds of the holders of the Series A and Series B redeemable convertible preferred stock, voting together as a single class. During the years ended December 31, 2022 and 2021, we have accreted \$1.8 million and \$6.5 million, respectively, to the redemption value of the redeemable convertible preferred stock representing cumulative dividends. Immediately prior to the closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock were converted into shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital. There were no shares of redeemable convertible preferred stock outstanding as of December 31, 2022.

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 II Item 8 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 \$99.3 million as of December 31, 2022, 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 charter.

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, most notably the Australian Dollar. 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, 2022.

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 of 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 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 Securities Exchange Act of 1934, as amended, or 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 Securities and Exchange Commission, or 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 principal executive and principal financial officers, 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, 2022, our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weaknesses in internal control over financial reporting.

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.

Previously Identified Material Weaknesses in Internal Control Over Financial Reporting

During the course of preparing for our IPO, we identified material weaknesses in our internal controls over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal controls 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 as of December 31, 2022 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.

The above material weaknesses resulted in adjustments to the redeemable convertible preferred stock, tranche liability and 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, or 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.

Remediation Plan

The Company is committed to remediating the material weakness to our internal control over financial reporting. We have implemented measures designed to improve our internal control over financial reporting to remediate these material weaknesses, including (i) the ongoing hiring of additional accounting personnel; (ii) designed and implemented internal controls in our financial control environment, including the establishment of formal accounting policies and procedures, financial reporting controls and controls to account for and disclose complex transactions; and (iii) implemented an accounting system upgrade with IT controls to insure appropriate and restricted access to our accounting applications, programs, and data, including upgrading of our accounting system.

Changes in Internal Control over Financial Reporting

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

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.

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.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Board Composition

Our business affairs are managed under the direction of our board of directors ("Board"), which is currently composed of nine members. Our directors are divided into three classes serving staggered three year terms. Upon expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three year term at the annual meeting of stockholders in the year in which their term expires. As a result of this classification of directors, it generally takes at least two annual meetings of stockholders for stockholders to effect a change in a majority of the members of our Board.

The names, ages, principal occupations and certain other information about the director nominees with terms expiring at the Annual Meeting and the additional members of our Board (including the skills and qualifications that led to the conclusion that they should serve as directors) are set forth below.

Name	Position(s)	Age
<i>Nominees:</i>		
Kabeer Aziz ⁽¹⁾	Class I Director	33
Gilbert Lynn Marks, M.D. ⁽²⁾	Class I Director	65
Rob Readnour, Ph.D. ⁽³⁾	Class I Director	59
<i>Continuing Directors:</i>		
Margaret FitzPatrick ⁽³⁾	Class II Director	57
Patricia Martin ⁽²⁾	Class II Director	62
Melvin Spigelman, M.D. ⁽²⁾	Class II Director	74
Eric Easom	President, Chief Executive Officer and Class III Director	55
Stephanie Wong ⁽¹⁾⁽³⁾	Class III Director	49
Joseph Zakrzewski ⁽¹⁾⁽³⁾	Class III Director	60

- (1) Member of the audit committee.
- (2) Member of the compensation committee.
- (3) Member of the nominating and corporate governance committee.

Nominees for Election to a Three-Year Term Ending at the 2026 Annual Meeting

Kabeer Aziz has served as a member of our Board since November 2019. In October 2018, Mr. Aziz co-founded Adjuvant Capital, a life sciences investment fund focused on global public health, and currently serves as a Principal and is responsible for sourcing, executing, and managing investments primarily focused on vaccines and therapeutics for infectious disease. Mr. Aziz currently serves as a member of the board of directors of MinervaX ApS, Pulmocide Ltd., Quantoom Biosciences S.A. and Frontier Nutrition, Inc. and is a board observer to Yisheng Biopharma Co., Ltd., each a healthcare company. From October 2015 to September 2018, Mr. Aziz was a Senior Associate at the Global Health Investment Fund, a healthcare focused impact fund. Prior to this, Mr. Aziz was an Investment Associate at Metalmark Capital from July 2013 to September 2015 as well as an Analyst at Greenhill & Co. from June 2011 to June 2013. Mr. Aziz received a B.S. in Finance and Economics from the Stern School of Business at New York University. We believe that Mr. Aziz's work in the infectious disease space and experience in healthcare finance makes him an appropriate member of our Board.

Gilbert Lynn Marks, M.D., has served as a member of our Board since February 2020. Dr. Marks has over 30 years of experience in the field of infectious diseases and as a senior executive in the pharmaceutical industry. Most recently, from September 2017 to September 2021, Dr. Marks was employed by Tunnell Government Services, Inc., or TGS, a subsidiary of Tunnell Consulting, Inc. that supports clients in medical product development, and became a Vice President at TGS in January 2020. As a contractor from TGS, Dr. Marks supported the Office of the Director for the Biomedical Advanced Research and Development Authority (BARDA) focusing on emerging infectious disease threats, antimicrobial resistance, and the clinical development of medical countermeasures. Previously, from 1993 to 2017, Dr. Marks led the infectious disease therapy area for GlaxoSmithKline for a decade and later retired as a Senior Vice President in R&D, with accountability as Chief Research Practices Officer across the Pharmaceutical, Vaccines, and Consumer Healthcare R&D organizations, as well as being Senior Clinical Advisor for Infectious Diseases. His extensive experience ranges across antibacterials, antivirals, including HIV/AIDS, and neglected tropical diseases. From 2006 to 2018, he has also served on the Scientific Advisory Board for the TB Alliance, a not-for-profit organization, including as Chair. In addition, from 2016 to 2021, Dr. Marks was a member of the Advisory Committee for the National Center for Advancing Translational Sciences at NIH and Chairs the Cures Acceleration Network Review Board for the National Center for Advancing Translational Sciences (NCATS). Since 2020, he has served on the Scientific Review Board for the Medicines for Malaria Venture (MMV), the leading not-for-profit product development partnership in the field of antimalarial drug research and development. Since 2009, he has served on the Scientific Advisory Committee for the Polio Antiviral Initiative. From 2017 through 2021, Dr. Marks served as a member of the Board of Directors for WOAR, Philadelphia, Pennsylvania's not for profit rape crisis support center. Dr. Marks' career began with a faculty position at the University of South Alabama College of Medicine in the Infectious Diseases group where he held teaching and patient care responsibilities, as well as a NIH-funded Physician Scientist Award investigating molecular mechanisms of bacterial pathogenicity. He is Board Certified in Internal Medicine and Infectious Diseases. Dr. Marks received a B.S. in Chemistry from Auburn University and an M.D. from University of South Alabama College of Medicine. We believe that Dr. Marks' over 30 years of experience in the field of infectious diseases and as a senior executive in the pharmaceutical industry makes him an appropriate member of our Board.

Rob Readnour, Ph.D., has served as a member of our Board since November 2019. Since July 2018, Dr. Readnour has served as the Managing Director at Mountain Group Partners, a venture capital firm that invests in early-stage companies in the life science, agricultural technology, and technology sectors. From October 1990 to June 2018, Dr. Readnour served in multiple senior management positions at Elanco Animal Health Incorporated, a publicly traded pharmaceutical company that was previously part of Eli Lilly, including Senior Director of Product Development and Senior Advisor and Chief Scientific Officer at Elanco Alternative Innovation. Dr. Readnour currently serves as a member of the board of or has visitation rights to Targan Inc., a bio-systems company focused on animal health, Advanced Animal Diagnostics, Inc., an animal health device company, Skyline Vet Pharma, Inc., a veterinary pharmaceutical company, Exubriion Therapeutics, Inc., a radiotherapeutic veterinary device company, Appello Pharmaceuticals, Inc., a drug development company, and NuSirt Biopharma, Inc., a drug and nutraceutical compound development company. Dr. Readnour also currently serves as the Executive Chairman of In the Bowl Animal Health, Inc., an animal health company. Dr. Readnour is also the Chief Executive Officer of Borah, Inc., an animal health discovery company. Dr. Readnour received a Ph.D. in Analytical Chemistry from University of Illinois and a B.S. in Chemistry from Southeast Missouri State University. We believe that Dr. Readnour's more than 30 years of experience moving products from discovery through commercialization makes him an appropriate member of our Board.

Directors Continuing in Office

Margaret (Maggie) FitzPatrick has served as a member of our Board since May 2022. Ms. FitzPatrick is a recognized leader in the area of corporate affairs, marketing and business operations. She has served in leadership positions in the public, private and non-profit sectors and brings a breadth of experience in healthcare, climate change and global health. Since July 2020, Ms. FitzPatrick has been the Founder and Chief Executive Officer of FitzPatrick & Co., a business advisory services firm providing leadership counseling, brand marketing and corporate affairs and advocacy. From 2016 to 2020, Ms. FitzPatrick served as Chief Corporate Affairs Officer for Exelon, a Fortune 200 clean energy provider. From 2013 to 2016, she served as Chief Communications Officer and VP of Public Affairs at Johnson & Johnson. From 2010 to 2013, Ms. FitzPatrick served as Chief Communications Officer and President of the Foundation at Cigna. Prior to that, Ms. FitzPatrick held multiple positions at APCO Worldwide, a global public affairs and strategic communications consultancy, including Executive Vice President. Ms. FitzPatrick is a member of the board of directors at VistaGen Therapeutics, a NASDAQ listed, late-stage central nervous system-focused biopharmaceutical company. Ms. FitzPatrick holds a B.A. in English and Public Policy from Syracuse University and a M.A. in Public Policy from The George Washington University. She completed the board directorship program at the Harvard Business School and is certified as a corporate director by the National Association of Corporate Directors. Appointed in 2020 by Mayor Muriel Bowser and approved by the Council of the District of Columbia, Ms. FitzPatrick serves as Commissioner and Vice Chairperson of the DC Commission on the Arts and Humanities. We believe that Ms. FitzPatrick is qualified to serve on our Board given her extensive experience in corporate affairs, public relations and marketing communications.

Patricia (Patty) Martin has served as a member of our Board since April 2021. From July 2019 through March 2023, Ms. Martin served as the President and Chief Executive Officer of BioCrossroads, a not-for-profit organization that supports and promotes the life sciences industry in the state of Indiana. Since July 2019, Ms. Martin has also served as the Managing Partner of BC Initiative, Inc., a company that supports seed fund investing in life sciences. From June 1991 to June 2017, Ms. Martin held multiple positions at Eli Lilly and Company, a publicly traded pharmaceutical company, or Eli Lilly, including Chief Operations Officer of Lilly Diabetes, Chief Diversity Officer and Chief Alliance Officer. Ms. Martin currently also serves as a member of the board of directors of CareSource, Inc., Flame Biosciences, Inc., Indiana Biosciences Research Institute, Indiana Health Information Exchange, Indiana University Foundation, Indiana University Research and Technology Corporation, Regenstrief Institute, and Christian Theological Seminary. Ms. Martin received a B.S. in Accounting from the Kelley School of Business at Indiana University and an M.B.A. from Harvard Business School. We believe that Ms. Martin's 25 years of experience as an executive at biopharmaceutical companies makes her an appropriate member of our Board.

Melvin Spigelman, M.D., has served as a member of our Board since February 2022. Since January 2009, Dr. Spigelman has served as President and Chief Executive Officer for the Global Alliance for TB Drug Development, a non-profit organization which seeks to accelerate the discovery and development of faster-acting and affordable drugs to fight tuberculosis. From June 2003 to June 2008, Dr. Spigelman served as a Director of Research and Development for the Global Alliance for TB Drug Development. Dr. Spigelman was also President of Hudson-Douglas Ltd, a consulting company, from June 2001 to June 2003. From 2000 to 2001, Dr. Spigelman served as a Vice President, Global Clinical Centers at Knoll Pharmaceuticals, a pharmaceutical unit of BASF Corporation, and from 1992 to 2000, Dr. Spigelman was the Vice President of Research and Development at Knoll Pharmaceuticals. Dr. Spigelman served as a director of The Medicines Company, a pharmaceutical company, from 2005 to 2018 and as director of Synergy Pharmaceuticals Inc., a pharmaceutical company, from 2005 to 2019. Dr. Spigelman received a B.A. in Engineering from Brown University and an M.D. from the Mount Sinai School of Medicine. We believe that Dr. Spigelman's expertise in drug development and management makes him an appropriate member of our Board.

Eric Easom has served as our President and Chief Executive Officer and a member of our Board since November 2019. From February 2009 to June 2017, Mr. Easom served as Vice President, Neglected Diseases at Anacor Pharmaceuticals, Inc., or Anacor, a publicly traded biopharmaceutical company that was acquired by Pfizer Inc. From July 2007 to January 2009, Mr. Easom served as the Senior Director, Business Development and Marketing at InteKrin Therapeutics, Inc., a biopharmaceutical company. From April 2006 to July 2007, he served as the Director of Marketing at MedImmune, a biotechnology company that was acquired by AstraZeneca. Mr. Easom currently serves as a member of the board of directors of the Chagas Disease Foundation and Resilient Biotics and is an advisor for the California Life Sciences Institute. Mr. Easom received a B.S. and M.S. in Electrical Engineering from the University of Louisville and an M.B.A. from Indiana University, Kelley School of Business. We believe that Mr. Easom's extensive work in high-growth biotechnology and pharmaceutical companies makes him an appropriate member of our Board.

Stephanie Wong has served as a member of our Board since April 2021. Ms. Wong has served as the Chief Financial Officer at Calithera Biosciences, Inc., or Calithera, a publicly traded biopharmaceutical company, since January 2021, and as Secretary since January 2017. Ms. Wong previously served in various roles at Calithera, as Senior Vice President, Finance from January 2018 to December 2020 and as Vice President, Finance from April 2014 to December 2017. Since December 2016, she has also served as a member of the board of directors of the Northern California Chapter of The Association of Bioscience Financial Officers, an association for financial executives working in the bioscience industry. From 2009 to 2013, Ms. Wong was at SciClone Pharmaceuticals, Inc., a publicly traded pharmaceutical company, most recently as Vice President, Finance and Controller. Prior to that, Ms. Wong served in senior finance roles at AcetRx Pharmaceuticals, Inc. and Kosan Biosciences, Inc., both biopharmaceutical companies, and as an audit manager at PricewaterhouseCoopers LLP, an independent registered public accounting firm. Ms. Wong received a B.S. in Business Administration from the University of California, Berkeley and is a Certified Public Accountant (inactive) in the state of California. We believe that Ms. Wong's extensive work in high-growth, publicly traded biopharmaceutical companies makes her an appropriate member of our Board.

Joseph Zakrzewski has served as a member of our Board since May 2017. Mr. Zakrzewski currently serves as the Chairman of the board of directors of Cerecin, Inc., a biopharmaceutical company and Cyteir Therapeutics, Inc., a publicly traded biotechnology company. Mr. Zakrzewski also currently serves as a member of the board of directors at Sangamo Therapeutics, Inc., a publicly traded biotechnology company, and Acceleron Pharma, a publicly traded biotechnology company. From January 2010 to June 2022, Mr. Zakrzewski served as a member of the board of directors of Amarin Corporation, a publicly traded biopharmaceutical company, or Amarin. From 2014 to 2020, Mr. Zakrzewski served as a member of the board of directors of SiteOne Therapeutics, Inc., a pharmaceutical company. From December 2009 to December 2013, Mr. Zakrzewski also served as the Chairman and Chief Executive Officer of Amarin. Mr. Zakrzewski received a B.S. in Chemical Engineering from Drexel University, an M.S. in Biochemical Engineering from Drexel University, and an M.B.A. in Finance from Indiana University. We believe that Mr. Zakrzewski's over 25 years of experience as an executive in the biotechnology and pharmaceutical industry makes him an appropriate member of our Board.

Board Committees and Meetings

Our Board has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our Board.

Audit Committee

The audit committee consists of Ms. Wong, Mr. Aziz and Mr. Zakrzewski. Ms. Wong is the chairperson of the Audit Committee and is the audit committee financial expert, as that term is defined under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act of 2002, and possesses financial sophistication, as defined under the rules of Nasdaq.

Although Mr. Aziz does not fall under the safe harbor provision of Rule 10A-3(e)(1)(ii) of the Exchange Act because Mr. Aziz is a limited partner of a stockholder that owns more than 10% of the Company's voting power, our Board has determined that each of Mr. Aziz, Mr. Zakrzewski, and Ms. Wong is independent.

Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the Board has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

Compensation Committee

The compensation committee consists of Ms. Martin, Dr. Marks, and Dr. Spigelman, each of whom meets the requirements for independence under current Nasdaq listing standards and SEC rules and regulations. Ms. Martin is the chairperson of the compensation committee. Each member of the compensation committee is also a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act. The compensation committee oversees our compensation policies, plans and benefits programs.

Compensation Committee Interlocks and Insider Participation

Our compensation committee consisted of Ms. Martin, Dr. Marks, and Dr. Spigelman for the year ended December 31, 2022. None of the members of the compensation committee is currently, or has been at any time, one of our officers or employees. During 2022, no member of our compensation committee or any of our executive officers has or had a relationship that would constitute an interlocking relationship, as defined under applicable SEC rules, with executive officers or directors of another entity.

Please refer to the section of this Annual Report on Form 10-K entitled “Certain Relationships and Related Transactions” for information concerning certain transactions involving members of the compensation committee.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee consists of Dr. Readnour, Ms. FitzPatrick, Ms. Wong and Mr. Zakrzewski, each of whom meets the requirements for independence under current Nasdaq listing standards and SEC rules and regulations. Dr. Readnour is the chairperson of the nominating and corporate governance committee. The nominating and corporate governance committee oversees and assists our Board in reviewing and recommending nominees for election as directors.

Identifying and Evaluating Director Nominees

Our Board has delegated to the nominating and corporate governance committee the responsibility of identifying individuals qualified to become board members and recommending to the Board nominees to fill vacancies and newly created directorships and the nominees to stand for election as directors. If the nominating and corporate governance committee determines that an additional or replacement director is required, it may take such measures that it considers appropriate in connection with its evaluation of a director candidate, including candidate interviews, inquiry of the person or persons making the recommendation or nomination, engagement of an outside search firm to gather additional information, or reliance on the knowledge of the members of the committee, the Board or management. In its evaluation of director candidates, including the members of the Board eligible for reelection, the nominating and corporate governance committee will consider the current size and composition of the Board and the needs of the Board and its committees. Some of the factors that our nominating and corporate governance committee considers include, without limitation, character, integrity, judgment, diversity, including diversity in terms of gender, race, ethnicity and experience, independence, area of expertise, corporate experience, length of service, potential conflicts of interest, other commitments and similar factors.

Nominees must also have the highest personal and professional ethics and integrity, proven achievement and competence in the nominee’s field and the ability to exercise sound business judgment, skills that are complementary to those of the existing Board, the ability to assist and support management and make significant contributions to the Company’s success, and an understanding of the fiduciary responsibilities that are required of a member of the Board and the commitment of time and energy necessary to diligently carry out those responsibilities.

A stockholder that wants to recommend a candidate for election to the Board should direct the recommendation in writing by letter to the Company, attention of the Corporate Secretary, at 1800 El Camino Real, Suite D, Menlo Park, California 94027. The recommendation must include the candidate’s name, home and business contact information, detailed biographical data, relevant qualifications, a signed letter from the candidate confirming willingness to serve, information regarding any relationships between the candidate and the Company and evidence of the recommending stockholder’s ownership of Company stock. Such recommendations must also include a statement from the recommending stockholder in support of the candidate, particularly within the context of the criteria for board membership. In addition, a stockholder must meet the deadlines and other requirements set forth in the Company’s bylaws. The nominating and corporate governance committee will consider candidates recommended by stockholders in the same manner as candidates recommended to the committee from other sources.

Corporate Governance Guidelines and Code of Business Conduct and Ethics

Our Board has adopted Corporate Governance Guidelines. These guidelines address items such as the qualifications and responsibilities of our directors and director candidates and corporate governance policies and standards applicable to us in general. In addition, our Board has adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer, and other executive and senior financial officers. The full text of our Corporate Governance Guidelines and our Code of Business Conduct and Ethics is posted on our website at <https://investor.an2therapeutics.com> in the Governance section of our Investors webpage. We intend to satisfy the disclosure requirements under Item 5.05 of the SEC Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website at the website address and location specified above.

Delinquent Section 16(A) Reports

Section 16(a) of the Exchange Act requires that our executive officers, directors and 10% stockholders file reports of ownership and changes of ownership with the SEC. Such directors, executive officers and 10% stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

SEC regulations require us to identify in this Annual Report on Form 10-K anyone who filed a required report late during the most recent fiscal year. Based solely on our review of forms we received and written representations of our executive officers, directors and 10% stockholders, we believe that during our fiscal year ended December 31, 2022, all Section 16(a) filing requirements were satisfied on a timely basis, other than the following exceptions: a late filing for Mr. Eizen was submitted on October 28, 2022, covering his initial grant upon hire.

Item 11. Executive Compensation.

Executive Officers

Name	Position(s)	Age
Eric Easom	Chief Executive Officer	55
Lucy Day	Chief Financial Officer	64
Sanjay Chanda, Ph.D.	Chief Development Officer	58
Paul Eckburg, M.D.	Chief Medical Officer	53
Joshua Eizen	Chief Legal Officer	45
Kevin Krause	Chief Strategy Officer	48

Information regarding Mr. Easom, who also serves as a director, is set forth above under “Directors and Corporate Governance.”

Lucy Day has served as our Chief Financial Officer since November 2019. From March 2002 to August 2016, Ms. Day served in various financial and administrative roles, including as the initial Chief Financial Officer, Vice President of Finance, and Vice President, Human Resources and Finance at Anacor. Ms. Day has previous experience at Centaur Pharmaceuticals, Inc., a biopharmaceutical company, including as Chief Financial Officer, Bank of America, Sohio Petroleum Company, and Ernst and Young LLP. Ms. Day received a B.A. in Political Economies from the University of California, Berkeley and is a CPA (inactive) in California.

Joshua Eizen, J.D., has served as our Chief Legal Officer since September 2022. From May 2021 to September 2022, Mr. Eizen served as Vice President, Associate General Counsel at Jazz Pharmaceuticals. From July 2018 to May 2021, Mr. Eizen served as Vice President, U.S. General Counsel for GW Pharmaceuticals plc. From May 2015 to June 2018, Mr. Eizen served as Senior Counsel, Chief Compliance Officer at Actelion (now Janssen Pulmonary Hypertension). From August 2008 to October 2014, Mr. Eizen served as Associate Chief Counsel at the U.S. Food and Drug Administration. From May 2003 to September 2008, Mr. Eizen was an Associate with the law firm of McKee Nelson (now Morgan Lewis). Mr. Eizen received a J.D. from Georgetown University Law Center and a B.A. and M.A. in Political Science and Government from Case Western Reserve University.

Sanjay Chanda, Ph.D., has served as our Chief Development Officer since November 2019. Since October 2017, Dr. Chanda has provided expert advice related to drug development through Sanjay Chanda Consulting Services. Since February 2017, Dr. Chanda has been serving as the Chief Development Officer at Cortene Inc., a biopharmaceutical company. Since January 2014, Dr. Chanda has also served as the Co-Founder and Development Consultant at Auration Biotech, Inc., a pharmaceutical company. From October 2016 to August 2017, he served as the Chief Development Officer of Tioma Therapeutics, Inc., an immune-oncology company. From January 2008 to October 2016, Dr. Chandra served as the Senior Vice President of Drug Development of Anacor. Dr. Chanda received a Ph.D. in Pharmacology and Toxicology from Northeast Louisiana University and an M. Pharmacy and B. Pharmacy from Birla Institute of Technology, Mesra, India.

Paul Eckburg, M.D., has served as our Chief Medical Officer since November 2019, initially as a 50% consultant and as a full-time employee as of April 30, 2021. Since 2000, he has been the owner of Eckburg Medical Consulting, a consulting company involved in anti-infective biopharmaceutical development. From August 2019 to May 2021, Dr. Eckburg served as an interim Chief Medical Officer and subsequent expert scientific advisor at SNIPR Biome ApS, a CRISPR microbiome company. From June 2016 to November 2022, he served as an interim Chief Medical Officer and subsequent scientific advisory board member at Bugworks Research Inc., a biopharmaceutical company. From July 2016 to April 2022, he has served as a consultant at Spero Therapeutics, Inc., a biopharmaceutical company. From February 2015 to August 2022, Dr. Eckburg has served as a consultant and Safety Monitoring Board member at Paratek Pharmaceuticals, Inc., a biopharmaceutical company. From February 2015 to September 2021, he has served as a scientific advisory board member for Cūrza Global, Inc., a biopharmaceutical company. From February 2018 to May 2019, he served as acting Chief Medical Officer at UTILITY Therapeutics Ltd., a biotechnology company. From April 2017 to May 2019, Dr. Eckburg served as the acting Vice President of Clinical Development at Recida Therapeutics, Inc., a biopharmaceutical company. From April 2016 to May 2019, he served as the acting Chief Medical Officer at Geom Therapeutics, Inc., a biopharmaceutical company. From March 2016 to July 2018, Dr. Eckburg served as the acting Chief Medical Officer at Zavante Therapeutics, Inc., a biopharmaceutical company, and continued as a consultant at Nabriva Therapeutics plc, a biopharmaceutical company, from June 2018 to June 2019. From September 2015 to January 2018, he served as the acting Chief Medical Officer at Nexgen Biosciences Inc., a biopharmaceutical company. From September 2013 to April 2017, Dr. Eckburg served as a consultant at MicuRx Pharmaceuticals, Inc., a biopharmaceutical company. From November 2012 to April 2016, he served as an ID Consultant at Genentech, Inc., a biotechnology company. Dr. Eckburg received an M.D. from Rush University and a B.S. in Cell and Structural Biology from the University of Illinois at Urbana-Champaign. He completed both an Internal Medicine residency and an Infectious Diseases fellowship at Stanford University School of Medicine, where he continues to teach as an Adjunct Clinical Assistant Professor.

Kevin Krause has served as our Chief Strategy Officer since August 2021. He was previously our Vice President of Clinical Sciences and Development Operations since November 2019. From January 2015 to June 2019, Mr. Krause served multiple roles at Achaogen, Inc., a biotechnology company, including the positions of Director of Microbiology, Senior Director, Head of Microbiology, and Senior Director of Corporate Development. From August 2010 to December 2014, Mr. Krause was a member of the Clinical Microbiology team at Cerexa, Inc., a biopharmaceutical company, and played a key role on the Scientific Assessment teams for all antibacterial and antiviral in-licensing opportunities. Prior to that, Mr. Krause worked at Theravance, Inc. from March 1999 to July 2010 in various research and clinical microbiology roles. Mr. Krause received an M.B.A. from the University of California, Berkeley Haas School of Business and a B.S. in Molecular Biology from San Francisco State University.

Summary Compensation Table

Our named executive officers for fiscal year ended December 31, 2022, which consist of our principal executive officer and the next two most highly compensated executive officers, are:

- Eric Easom, our President and Chief Executive Officer;
- Joshua Eizen, J.D., our Chief Legal Officer; and
- Paul Eckburg, M.D., our Chief Medical Officer.

The following table sets forth information regarding the total compensation for services rendered in all capacities that was earned by our named executive officers in the year indicated.

Name and Principal Position	Year	Salary (\$)	Option Awards (\$) ⁽¹⁾	Non-Equity Incentive Plan Compensation (\$) ⁽²⁾	Total (\$)
Eric Easom <i>President, Chief Executive Officer and Director</i>	2022	481,185	2,767,815	216,533	3,465,533
	2021	377,300	1,190,689	151,000	1,718,989
Paul Eckburg, M.D. ⁽³⁾ <i>Chief Medical Officer</i>	2022	427,399	811,893	153,864	1,393,156
	2021	258,125	567,928	77,000	903,053
Joshua Eizen, J.D. ⁽⁴⁾ <i>Chief Legal Officer</i>	2022	101,742	1,216,194	36,627	1,354,563

- (1) The amounts reported represent the aggregate grant date fair value of the awards, calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 — Compensation — Stock Compensation (“ASC 718”), excluding the effect of any estimated forfeitures. Information about the assumptions used in the calculation of these amounts are included in “Note 2. *Summary of Significant Accounting Policies — Stock-Based Compensation*” and “Note 10. *Equity Incentive Plan and Stock-Based Compensation*” to the Company’s financial statements for the year ended December 31, 2022 included in the Company’s Annual Report on Form 10-K for such year.
- (2) Non-equity incentive plan compensation consists of bonus awards under the Incentive Compensation Plan (as defined below) earned for 2022 and 2021 performance, which compensation was paid in March 2023 and March 2022, respectively.
- (3) Dr. Eckburg commenced employment with us on April 30, 2021. Prior to his employment, Dr. Eckburg was a consultant for us.
- (4) Mr. Eizen commenced employment with us on September 29, 2022, and his non-equity incentive plan compensation earned was prorated for his time employed by the Company in 2022.

Narrative to Summary Compensation Table

Our compensation committee reviews compensation annually for all executive employees, including our named executive officers. In making compensation determinations, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our Company. For setting our 2022 executive compensation levels, our compensation committee also engaged Aon as compensation consultants to develop a comparative peer group of companies and to perform analyses of our executive compensation practices compared with current market practices and the peer group of companies.

Our compensation committee has historically determined our executive officers’ compensation and has typically reviewed and discussed management’s proposed compensation with our Chief Executive Officer for all executives other than our Chief Executive Officer. Based on those discussions and its discretion, our compensation committee then approved the compensation of each executive officer.

Annual Base Salaries

Base salaries for our executive officers are initially established through arm’s-length negotiations at the time of the executive officer’s hiring, taking into account such executive officer’s qualifications, experience, the scope of his or her responsibilities and competitive market compensation paid by other companies for similar positions within the industry and geography. Base salaries are reviewed periodically, typically in connection with our annual review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. In making decisions regarding salary increases, especially in connection with our initial public offering, we reviewed the analysis conducted by Aon comparing our compensation practices to current market practices and those of our peer group of companies. The 2022 and 2021 base salaries for our named executive officers are reflected in the table above, as adjusted or prorated throughout the year based on respective start dates, except no base salary is reported for Mr. Eizen for 2021 given he joined us in 2022.

Non-Equity Incentive Plan Compensation

Each of our named executive officers was eligible to receive an annual incentive bonus based on the attainment of corporate objectives for the fiscal year ended December 31, 2022, approved by our Board in February 2023. The target bonus for each of Mr. Easom, Dr. Eckburg and Mr. Eizen was 50%, 40% and 40% of his base salary, respectively. The compensation committee of our Board has the authority, in its sole discretion and at any time, to increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. In February 2023, the Board assessed our performance against our 2022 corporate goals and, based on such performance, awarded a cash annual incentive bonus to each of Mr. Easom, Dr. Eckburg and Mr. Eizen equal to 90% of his target bonus amount for 2022.

For 2021, each of our named executive officers (other than Mr. Eizen who joined us in 2022) was eligible to receive an annual incentive bonus based on the achievement of certain of our 2021 corporate goals. The target bonus for each of Mr. Easom and Dr. Eckburg was 40% and 30% of his base salary, respectively. In February 2022, our Board assessed Company performance against our 2021 corporate goals and based on such performance, awarded a cash annual incentive bonus to each of our named executive officers (other than Mr. Eizen) equal to 100% of his target bonus amount for 2021. These bonuses were paid in early 2022.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and those of our stockholders with those of our employees and consultants, including our executive officers. Our Board or an authorized committee thereof is responsible for approving equity grants. Historically, we have generally used stock options as an incentive for long-term compensation to our executive officers because stock options allow our executive officers to profit from this form of equity compensation only if our stock price increases relative to the stock option's exercise price, which exercise price is set at the fair market value of our common stock on the date of grant.

We may grant equity awards at such times as our Board or compensation committee determines appropriate. Our executives generally are awarded an initial grant in the form of a stock option in connection with their commencement of employment with us. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Prior to our initial public offering, we granted all stock options pursuant to our Amended and Restated 2017 Equity Incentive Plan (the "2017 Plan"). All equity incentive awards granted since our initial public offering have been granted pursuant to our 2022 Equity Incentive Plan (the "2022 Plan").

All stock options are granted with an exercise price per share that is no less than the fair market value of our common stock on the date of grant of such award. Our stock option awards granted to our named executive officers generally vest over a four-year period and may be subject to acceleration of vesting and exercisability under certain termination and change in control events, as described in more detail under the subsections below titled "Employment Arrangements" and "Potential Payments and Benefits upon Termination or Change in Control."

In May 2022, our Board granted to Mr. Easom and Dr. Eckburg an option to purchase 225,000 and 66,000 shares of our common stock, respectively, at an exercise price of \$17.28 per share. The shares shall vest in 48 monthly increments commencing on the one-month anniversary of the vesting commencement date of March 25, 2022, subject to continued service to the Company through each such vesting date. In October 2022, our Board granted to Mr. Eizen an option to purchase 92,000 shares of our common stock at an exercise price of \$17.88 per share. 25% of the shares shall vest on the one-year anniversary of the vesting commencement date of September 29, 2022, and the remainder vest on a monthly basis thereafter, subject to continued service to the Company through each such vesting date. The option grants are set forth in the Outstanding Equity Awards at December 31, 2022 in the table below.

In April 2021, our Board granted to Mr. Easom and Dr. Eckburg an option to purchase 249,999 and 118,999 shares of our common stock, respectively, at an exercise price of \$6.60 per share. Mr. Easom's shares shall vest in 48 monthly increments commencing on the one-month anniversary of the vesting commencement date, subject to continued service to the Company through each such vesting date. Mr. Eckburg's shares shall vest 25% on the one-year anniversary of the vesting commencement date, and the remainder vest on a monthly basis thereafter. The option grants are set forth in the Outstanding Equity Awards at December 31, 2022 in the table below.

Named Executive Officer Employment Arrangements

Eric Easom

We entered into an employment offer letter with Eric Easom, our President and Chief Executive Officer, on November 19, 2019. The employment offer letter has no specific term and provides that Mr. Easom is an at-will employee. Mr. Easom's current base salary is \$575,000 and his target annual cash bonus is equal to 50% of his annual base salary.

Paul Eckburg, M.D.

We entered into an employment offer letter with Paul Eckburg, our Chief Medical Officer, on April 30, 2021. The employment offer letter has no specific term and provides that Dr. Eckburg is an at-will employee. Dr. Eckburg's current base salary is \$465,000 and his target annual cash bonus is equal to 40% of his annual base salary.

In connection with the commencement of his employment, Dr. Eckburg was granted an option to purchase 118,999 shares of common stock, 25% of which vest on the one-year anniversary of the vesting commencement date, and the remainder vesting on a monthly basis thereafter, subject to continued service to us through each such vesting date.

Joshua Eizen

We entered into an employment offer letter with Joshua Eizen, our Chief Legal Officer, on September 19, 2022. The employment offer letter has no specific term and provides that Mr. Eizen is an at-will employee. Mr. Eizen's current base salary is \$410,000 and his target annual cash bonus is equal to 40% of his annual base salary, which amount was pro-rated for his date of hire in respect of the 2022 year.

In connection with the commencement of his employment, in September 2022, Mr. Eizen was granted an option to purchase 92,000 shares of common stock, 25% of which vest on the one-year anniversary of the vesting commencement date of September 29, 2022, and the remainder vesting on a monthly basis thereafter, subject to continued service to us through each such vesting date.

Each named executive officer is eligible for severance and change of control-related benefits as described below.

Potential Payments and Benefits upon Termination or Change in Control

Our Board has adopted a Severance and Change in Control Plan ("Severance Plan"), in which our named executive officers, and certain other executives, participate. The benefits provided in the Severance Plan replace any severance for which our named executive officers may be eligible under their existing offer letters or other employment agreements or arrangements, except to the extent such offer letters or other agreements or arrangements provide for greater benefits; provided, that, the defined terms in the Severance Plan supersede the corresponding defined terms or other similar terms in such offer letter or other agreements or arrangements.

The Severance Plan provides that upon a termination by us for any reason other than for "cause," as defined in the Severance Plan, death or "disability," as defined in the Severance Plan, outside of the change in control period (i.e., the period starting three months before and ending one year after a "change in control," as defined in the Severance Plan), an eligible participant will be entitled to receive, subject to the execution and delivery of an effective release of claims in favor of our company and continued compliance with all applicable restrictive covenants, (i) a lump sum amount equal to 100% of the annual base salary in effect immediately prior to the date of termination for our Chief Executive Officer and 75% of the annual base salary in effect immediately prior to the date of termination for our other named executive officers, (ii) an additional cash lump sum equal to any earned but unpaid annual bonus for any performance years that were completed as of the date of termination, and (iii) if the named executive officer timely elects, continued group health plan continuation coverage under the Consolidated Omnibus Budget Reconciliation Act, or COBRA, the premiums on behalf of such officer and any eligible dependents for 12 months following termination for our Chief Executive Officer and nine months following termination for our other named executive officers. The payments under (i) and (ii) will be paid within 30 days after the delivery of an effective release of claims by the named executive officers.

The Severance Plan also provides that upon a (A) termination by us other than for cause, death or disability or (B) resignation for “good reason,” as defined in the Severance Plan, in each case within the change in control period, an eligible participant will be entitled to receive, in lieu of the payments and benefits above and subject to the execution and delivery of an effective release of claims in favor of our company and continued compliance with all applicable restrictive covenants, (i) a lump sum amount equal to 150% of the base salary and 150% of the target annual bonus in effect immediately prior to the date of termination for our Chief Executive Officer and 100% of the base salary and 100% of the target annual bonus in effect immediately prior to the date of termination for our other named executive officers, (ii) an additional cash lump sum equal to any earned but unpaid annual bonus for any performance years that were completed as of the date of termination, (iii) if the named executive officer timely elects continued group health plan continuation coverage, the COBRA premiums on behalf of such officer and any eligible dependents for 18 months following termination for our Chief Executive Officer and 12 months following termination for our other named executive officers, and (iv) for all outstanding and unvested equity awards of our company that are subject to vesting held by the participant, full accelerated vesting of such awards; provided, that the performance conditions applicable to any outstanding and unvested equity awards subject to performance-based vesting will be deemed satisfied at the target level specified in the terms of the applicable award agreement.

The payments and benefits provided under the Severance Plan in connection with a change in control may not be eligible for a federal income tax deduction by us pursuant to Section 280G of the Code. These payments and benefits may also subject an eligible participant, including the named executive officers, to an excise tax under Section 4999 of the Code. If the payments or benefits payable in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to the participant.

Outstanding Equity Awards as of December 31, 2022

The following table shows outstanding equity awards held by our named executive officers as of December 31, 2022:

Named Executive Officer	Grant Date	Vesting Commencement Date	Option Awards ⁽¹⁾		Option Exercise Price (\$)	Option Expiration Date
			Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)		
Eric Easom	04/30/2021 ⁽²⁾	04/30/2021	104,166	145,833	6.60	04/29/2031
	05/12/2022 ⁽³⁾	03/25/2022	42,187	182,813	17.28	05/11/2032
Joshua Eizen, J.D.	10/14/2022 ⁽⁴⁾	09/29/2022	—	92,000	17.88	10/13/2032
Paul Eckburg, M.D.	01/23/2020 ⁽⁵⁾	11/21/2019	—	—	—	—
	10/05/2020 ⁽⁶⁾	10/05/2020	4,418	—	0.42	09/23/2030
	04/30/2021 ⁽⁷⁾	04/30/2021	49,582	69,417	6.60	04/29/2031
	05/12/2022 ⁽⁸⁾	03/25/2022	12,375	53,625	17.28	05/11/2032

- (1) All of the option awards granted prior to March 24, 2022 were made under the Amended and Restated 2017 Equity Incentive Plan and all grants made subsequent to March 24, 2022 were made under our 2022 Equity Incentive Plan.
- (2) The option vests in respect of 1/48th of the underlying shares on each monthly anniversary of the vesting commencement date, subject to Mr. Easom’s continued service with us through each vesting date. As of December 31, 2022, 104,166 shares were vested and 145,833 shares were not vested. The option is subject to the vesting acceleration provision described below under “—Potential Payments and Benefits upon Termination or Change in Control.”
- (3) The option vests in respect of 1/48th of the underlying shares on each monthly anniversary of the vesting commencement date, subject to Mr. Easom’s continued service with us through each vesting date. As of December 31, 2022, 42,187 shares were vested and 182,813 shares were not vested. The option is subject to the vesting acceleration provision described below under “—Potential Payments and Benefits upon Termination or Change in Control.”

- (4) The option vests in respect of 25% of the underlying shares on the first anniversary of the vesting commencement date, with the remaining 75% of the underlying shares vesting on a monthly basis thereafter, subject to Mr. Eizen's continued service with us through each vesting date. As of December 31, 2022, 92,000 shares were not vested. The option is subject to the vesting acceleration provision described below under "—Potential Payments and Benefits upon Termination or Change in Control."
- (5) Dr. Eckburg acquired 18,289 shares of our common stock pursuant to a common stock option agreement. As of December 31, 2022, all shares were vested.
- (6) The option vests in respect of 1/12th of the underlying shares on each monthly anniversary of the vesting commencement date, subject to Dr. Eckburg's continued service with us through each vesting date. As of December 31, 2022, all shares were vested.
- (7) The option vests in respect of 25% of the underlying shares on the first anniversary of the vesting commencement date, with the remaining 75% of the underlying shares vesting on a monthly basis thereafter, subject to Dr. Eckburg's continued service with us through each vesting date. As of December 31, 2022, 49,582 shares were vested and 69,417 shares were not vested. The option is subject to the vesting acceleration provision described below under "—Potential Payments and Benefits upon Termination or Change in Control."
- (8) The option vests in respect of 1/48th of the underlying shares on each monthly anniversary of the vesting commencement date, subject to Dr. Eckburg's continued service with us through each vesting date. As of December 31, 2022, 12,375 shares were vested and 53,625 shares were not vested. The option is subject to the vesting acceleration provision described below under "—Potential Payments and Benefits upon Termination or Change in Control."

Other Compensation and Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental and vision plans, in each case on the same basis as all of our other employees. We pay the premiums for the medical, disability, and accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers.

401(k) Plan

We maintain a 401(k) retirement savings plan for the benefit of our employees. Under the 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code, on a pre-tax or after-tax (Roth) basis, through contributions to the 401(k) plan. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) plan.

Emerging Growth Company Status

We became a public company in March 2022 and we are an "emerging growth company" under applicable federal securities laws and therefore permitted to take advantage of certain reduced public company reporting requirements. As an emerging growth company, we provide in this Annual Report on Form 10-K the scaled disclosure permitted under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, including certain executive compensation disclosures required of a "smaller reporting company," as that term is defined in Rule 12b-2 promulgated under the Exchange Act. In addition, as an emerging growth company, we are not required to conduct votes seeking approval, on an advisory basis, of the compensation of our named executive officers or the frequency with which such votes must be conducted. We will remain an emerging growth company until the earliest of (i) December 31, 2027, (ii) the last day of the first fiscal year in which our annual gross revenue is \$1.235 billion or more, (iii) the date on which we have, during the previous rolling three-year period, issued more than \$1.235 billion in non-convertible debt securities, or (iv) the date on which we are deemed to be a "large accelerated filer" as defined in the Exchange Act.

Equity Compensation Plan Information

The following table provides information as of December 31, 2022 with respect to shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options	Weighted Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)
Equity compensation plans approved by security holders			
2017 Amended and Restated Equity Incentive Plan ⁽¹⁾	1,354,727	7.25	—
2022 Equity Incentive Plan ⁽²⁾	1,164,720	15.79	705,280
2022 Employee Stock Purchase Plan ⁽³⁾	—	N/A	187,000
Total	2,519,447	N/A	892,280

- (1) As a result of the adoption of the 2022 Plan, we no longer grant awards under the 2017 Plan; however, all outstanding options issued pursuant to the 2017 Plan continue to be governed by their existing terms. To the extent that any such awards are forfeited or lapse unexercised or are repurchased, the shares of common stock subject to such awards will become available for issuance under the 2022 Plan.
- (2) The 2022 Plan provides that the number of shares available for issuance under the 2022 Plan will be increased on the first day of each fiscal year for a period of ten years beginning with the 2023 fiscal year, in an amount equal to the least of (i) four percent (4%) of the outstanding shares of common stock on the last day of the immediately preceding fiscal year or (ii) such other amount as our Board or any of its committees as will be administering the 2022 Plan may determine. Pursuant to these terms, an additional 776,106 shares were added to the number of available shares under the 2022 Plan effective January 1, 2023.
- (3) The 2022 ESPP provides that the number of shares available for issuance under the 2022 ESPP will be increased on the first day of each fiscal year beginning in 2023 in an amount equal to the least of (i) one percent (1%) of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, (ii) 561,000 shares of common stock or (iii) such other amount as may be determined by our Board or any of its committees as will be administering the 2022 ESPP may determine. Pursuant to these terms, an additional 194,026 shares were added to the number of available shares under the 2022 ESPP effective January 1, 2023.

Compensation of Non-Employee Directors

The following table sets forth information concerning compensation earned by the non-employee members of our Board in fiscal year 2022. Mr. Easom, our President and Chief Executive Officer, is also a director but does not receive any additional compensation for his services as a director. Information concerning the compensation earned by Mr. Easom is set forth in the section titled “Executive Compensation.”

Name	Fees Earned (\$)	Option Awards (\$)(1)(2)	Total (\$)
Kabeer Aziz	31,875	252,207	284,082
Margaret FitzPatrick ⁽³⁾	26,000	123,030	149,030
Gilbert Lynn Marks, M.D.	38,125	122,734	160,859
Patricia Martin	43,750	122,734	166,484
Rob Readnour, Ph.D.	32,250	252,207	284,457
Melvin Spigelman, M.D.	38,125	122,734	160,859
Stephanie Wong	46,750	122,734	169,484
Joseph Zakrzewski ⁽⁴⁾	77,576	122,734	200,310

- (1) The amounts reported represent the aggregate grant date fair value of the awards, calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718—Compensation—Stock Compensation (“ASC 718”), excluding the effect of any estimated forfeitures. Information about the assumptions used in the calculation of these amounts are included in “Note 2. Summary of Significant Accounting Policies—Stock-Based Compensation” and “Note 10. Equity Incentive Plan and Stock-Based Compensation” to the Company’s financial statements for the year ended December 31, 2022 included in this Annual Report on Form 10-K for such year.
- (2) The following table lists all outstanding option awards held by our non-employee directors as of December 31, 2022:

Name	Option Awards
Kabeer Aziz	20,724
Margaret FitzPatrick ⁽³⁾	10,362
Gilbert Lynn Marks, M.D.	21,027
Patricia Martin	35,361
Rob Readnour, Ph.D.	20,724
Melvin Spigelman, M.D.	27,303
Stephanie Wong	35,361
Joseph Zakrzewski ⁽⁴⁾	110,361

- (3) Ms. FitzPatrick joined the Board effective May 5, 2022.
- (4) In the first quarter of 2022, Mr. Zakrzewski was paid according to his Board Chair Letter agreement. In the remaining quarters of 2022 his fee was adjusted to conform to the Non-Employee Director Compensation Policy.

We also reimburse our non-employee directors for their reasonable out-of-pocket costs and travel expenses in connection with their attendance at Board and committee meetings.

Non-Employee Director Compensation Policy

Our Board adopted a non-employee director compensation policy (the “Director Compensation Policy”), effective as of March 24, 2022. Under the Director Compensation policy, each non-employee director is eligible to receive compensation for his or her service consisting of the following annual cash retainers and equity awards. Our Board has the discretion to revise non-employee director compensation as it deems necessary or appropriate.

Cash Compensation

All non-employee directors are entitled to receive the following cash compensation for their services:

- \$35,000 per year for services as a Board member;
- \$30,000 per year additionally for service as chairman of the Board;

- \$15,000 per year additionally for service as chairman of the audit committee or \$7,500 per year additionally for service as an audit committee member;
- \$15,000 per year additionally for service as chairman of the compensation committee or \$7,500 per year additionally for service as a compensation committee member; and
- \$8,000 per year additionally for service as chairman of the nominating and corporate governance committee or \$4,000 per year additionally for service as a nominating and corporate governance committee member.

For clarity, each non-employee director who serves as the chair of a committee will receive only the annual fee for services as the chair of the committee and not the additional annual fee for services as a member of the committee, provided that the non-employee director who serves as the chairman of the Board will receive the annual fee for services as the chairman of the Board and the annual fee for services as a Board member.

Equity Compensation

All non-employee directors are entitled to receive all types of awards (except incentive stock options) under the 2022 Plan including discretionary awards not covered under the Director Compensation Policy. Automatic grants of stock options are made to our non-employee directors as follows:

- *Initial Award.* Upon joining the Board, each newly-elected non-employee director will be granted a one-time grant (the "Director Initial Grant") of a non-statutory stock option with a grant-date value of \$209,093 on the date of such director's election or appointment to the Board. The Director Initial Grant will vest in substantially equal monthly installments over three years, subject to continued service as a Service Provider through each vesting date.
- *Annual Award.* Each non-employee director (including the chairman of the Board) will be granted an annual award (the "Director Annual Grant") of a non-statutory stock award with a grant-date value of \$104,546; provided however, that any director who receives a Director Initial Grant at least three months, but less than six months, prior to the annual meeting stockholders of our company will be granted an award of a non-statutory stock option with a grant-date value of \$52,273. The Director Annual Grant will vest in full on the earlier of the one-year anniversary of the grant date or on the date of our next annual meeting of stockholders, subject to continued service as a Service Provider through each vesting date. The Director Initial Grant and Director Annual Grant are subject to full acceleration vesting upon the sale of our company.

Pursuant to the Director Compensation Policy, no non-employee director may be issued, in any fiscal year, cash compensation and equity awards with an aggregate value greater than \$750,000. Any cash compensation paid or equity awards granted to an individual for his or her services as an employee, for his or her services as a consultant (other than as a non-employee director), will not count for purposes of this limitation.

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

Beneficial Ownership of Shares of Common Stock

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 15, 2023 for:

- each beneficial owner of 5% or more of the outstanding shares of our common stock;
- each of our directors;
- each of our named executive officers; and
- all directors and executive officers as a group.

The number of shares of common stock beneficially owned by each person or entity is determined in accordance with the applicable rules of the SEC and includes voting or investment power with respect to shares of our common stock. The information is not necessarily indicative of beneficial ownership for any other purpose. Unless otherwise indicated, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under community property laws. The inclusion herein of any shares as beneficially owned does not constitute an admission of beneficial ownership.

Applicable percentage ownership is based on 19,402,658 shares of common stock outstanding at March 15, 2023. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable within 60 days of March 15, 2023. However, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Shares Outstanding
Five Percent Stockholders:		
Entities affiliated with RA Capital Healthcare Fund ⁽¹⁾	3,773,517	19.45%
Entities affiliated with Adjuvant Global Health Technology Fund ⁽²⁾	2,597,380	13.39%
Entities affiliated with Biotechnology Value Fund ⁽³⁾	1,563,963	8.06%
Anacor Pharmaceuticals, LLC ⁽⁴⁾	1,362,499	7.02%
Entities affiliated with Citadel Advisors ⁽⁵⁾	1,336,993	6.89%
Brii Biosciences Limited ⁽⁶⁾	1,048,479	5.40%
Directors and Named Executive Officers:		
Eric Easom ⁽⁷⁾	1,390,725	7.17%
Paul Eckburg, M.D. ⁽⁸⁾	100,081	*
Joshua Eizen, J.D.	—	—
Kabeer Aziz ⁽⁹⁾	7,483	*
Margaret FitzPatrick ⁽¹⁰⁾	10,362	*
Gilbert Lynn Marks, M.D. ⁽¹¹⁾	40,302	*
Patricia Martin ⁽¹²⁾	27,028	*
Melvin Spigelman, M.D. ⁽¹³⁾	17,420	*
Rob Readnour, Ph.D. ⁽¹⁴⁾	912,438	4.70%
Stephanie Wong ⁽¹⁵⁾	27,028	*
Joseph Zakrzewski ⁽¹⁶⁾	681,107	3.51%
All executive officers and directors (14 persons) ⁽¹⁷⁾	3,595,254	18.53%

* Represents beneficial ownership of less than 1%.

- (1) Based solely on information set forth in a Schedule 13G filed with the SEC on February 14, 2023 by RA Capital Management, L.P. ("RA Capital") and RA Capital Healthcare Fund, L.P. (the "Fund"). Consists of (i) 3,357,905 shares of common stock held by the Fund and (ii) 415,612 shares of common stock held by RA Capital Nexus Fund, L.P. (the "Nexus Fund"). RA Capital Healthcare Fund GP, LLC is the general partner of the Fund and RA Capital Nexus Fund GP, LLC is the general partner of the Nexus Fund. The general partner of RA Capital is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the controlling persons. RA Capital serves as investment adviser for the Fund and the Nexus Fund and may be deemed a beneficial owner of any securities of the Company held by the Fund and the Nexus Fund. As managers of RA Capital, Peter Kolchinsky and Rajeev Shah have the power to vote or dispose of the shares held by the Fund and Nexus Fund. The Schedule 13G filed by RA Capital, Peter Kolchinsky, Rajeev Shah, and the Fund provides information as of December 31, 2022 and, consequently, the beneficial ownership of the reporting entities may have changed between December 31, 2023 and March 15, 2023. The address of the persons and entities listed above is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

- (2) Consists of (i) 2,184,224 shares of common stock held by Adjuvant Global Health Technology Fund L.P. and (ii) 413,156 shares of common stock held by Adjuvant Global Health Technology Fund DE, L.P. Adjuvant Capital GP, L.P. has shared voting and shared dispositive power over the shares held by Adjuvant Global Health Technology Fund DE L.P. Adjuvant Capital GP, L.P. is the sole general partner of Adjuvant Global Health Technology Fund L.P. and Adjuvant Global Health Technology Fund DE, L.P. and may be deemed to beneficially own the shares of Common Stock beneficially owned by Adjuvant Global Health Technology Fund L.P. and Adjuvant Global Health Technology Fund DE, L.P. Adjuvant Capital Management, L.L.C. is the sole general partner of Adjuvant Capital GP, L.P. and may be deemed to beneficially own the shares of Common Stock beneficially owned by Adjuvant Global Health Technology Fund L.P. and Adjuvant Global Health Technology Fund DE, L.P. Adjuvant Capital GP, L.P. has shared voting and shared dispositive power over the shares held by Adjuvant Global Health Technology Fund L.P. and Adjuvant Global Health Technology Fund DE L.P. Kabir Aziz is a limited partner of Adjuvant Capital GP, L.P. and shares voting and dispositive power over the shares held by Adjuvant Global Health Technology Fund, L.P. and Adjuvant Global Health Technology Fund DE, L.P. Mr. Aziz, however, disclaims beneficial ownership of such shares of common stock, except to the extent of any pecuniary interest therein. The address of the persons and entities listed above is 500 Fifth Avenue, Suite 5120, New York, New York 10110.
- (3) Based solely on information set forth in a Schedule 13G filed with the SEC on February 14, 2023 by Biotechnology Value Fund, L.P. ("BVF"), BVF I GP LLC ("BVF GP"), Biotechnology Value Fund II, L.P. ("BVF2"), BVF II GP LLC ("BVF2 GP"), BVF Partners OS Ltd. ("Partners OS"), Biotechnology Value Trading Fund OS LP ("Trading Fund OS"), BVF GP Holdings LLC ("BVF GPH"), BVF Partners L.P. ("Partners"), BVF Inc., and Mark N. Lampert (collectively, the "BVF entities"). Consists of (i) 846,993 shares of common stock held by BVF, (ii) 616,777 shares of common stock held by BVF2, (iii) 89,084 shares of common stock held by Trading Fund OS, and (iv) 11,109 shares of common stock held by in a certain account managed by BVF Partners OS Ltd. ("Partners OS"). BVF I GP LLC ("BVF GP") is the general partner of BVF. BVF II GP LLC ("BVF2 GP") is the general partner of BVF2. Partners OS is the general partner of Trading Fund OS. BVF GP Holdings LLC ("BVF GPH") is the sole member of each of BVF GP and BVF2 GP and may be deemed to beneficially own all shares beneficially owned in the aggregate by BVF and BVF2. BVF Partners L.P. ("Partners"), as the investment manager of BVF, BVF2 and Trading Fund OS, and the sole member of Partners OS, may be deemed to beneficially own the 1,563,963 Shares beneficially owned in the aggregate by BVF, BVF2 and Trading Fund OS and held in a certain Partners managed account (the "Partners Managed Account. BVF Partners L.P. ("Partners"), as the investment manager of BVF, BF2, and Trading Fund OS, and the sole member of Partners OS, may be deemed to beneficially own all shares beneficially owned in the aggregate by BVF, BVF2, Trading Fund OS, and Partners OS. BVF Inc., as the general partner of Partners, may be deemed to beneficially own all shares of common stock beneficially owned by the Partners. Mark N. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own all shares of common stock beneficially owned by BVF Inc. The Schedule 13G filed by the BVF entities provides information as of December 31, 2022 and, consequently, the beneficial ownership of the reporting entities may have changed between December 31, 2022 and March 15, 2023. The business address of BVF, BVF GP, BVF2, BVF2 GP, BVF GPH, Partners, BVF Inc., and Mr. Lampert is 44 Montgomery St., 40th Floor, San Francisco, California 94104. The business address of Trading Fund OS and Partners OS is PO Box 309 Ugland House, Grand Cayman, KY1-1104, Cayman Islands.
- (4) Based solely on information set forth in a Schedule 13G filed with the SEC on February 13, 2023 by Pfizer Inc. and Anacor Pharmaceuticals, LLC. Consists of shares of common stock held by Anacor Pharmaceuticals, LLC. Pfizer Inc. may be deemed to have beneficial ownership over shares of common stock held by Anacor Pharmaceuticals, LLC since Anacor Pharmaceuticals, LLC is a wholly-owned subsidiary of Pfizer Inc. The Schedule 13G filed by Anacor Pharmaceuticals, LLC provides information as of December 31, 2022 and, consequently, the beneficial ownership of Anacor Pharmaceuticals, LLC may have changed between December 31, 2022 and March 15, 2023. The principal business address for Anacor Pharmaceuticals, LLC is c/o Pfizer Inc. 235 East 42nd Street, New York, New York 10017.

- (5) Based solely on information set forth in a Schedule 13G filed with the SEC on February 14, 2023 by Citadel Advisors LLC, Citadel Advisors Holdings LP, Citadel GP LLC, Citadel Securities LLC, Citadel Securities Group LP, Citadel Securities GP LLC, and Kenneth Griffin (collectively, "Citadel"). Consists of (i) 1,336,983 shares of common stock beneficially owned by Citadel Multi-Strategy Equities Master Fund Ltd., a Cayman Islands company ("CM") and (ii) 10 shares of common stock beneficially owned by Citadel Securities LLC. Citadel Advisors LLC is the portfolio manager for CM. Citadel Advisors Holdings LP is the sole member of Citadel Advisors LLC. Citadel GP LLC is the general partner of Citadel Advisors Holdings LP. Citadel Securities Group LP is the non-member manager of Citadel Securities LLC. Citadel Securities GP LLC is the general partner of Citadel Securities Group LP. Mr. Griffin is the President and Chief Executive Officer of Citadel GP LLC, and owns a controlling interest in Citadel GP LLC and Citadel Securities GP LLC. The Schedule 13G filed by Citadel provides information as of December 31, 2022 and, consequently, the beneficial ownership of the reporting entities may have changed between December 31, 2022 and March 15, 2023. The business address of Citadel is Southeast Financial Center, 200 S. Biscayne Blvd., Suite 3300, Miami, Florida 33131.
- (6) Based solely on information set forth in a Schedule 13G filed with the SEC on February 13, 2023 by Bii Biosciences Limited. Consists of shares of common stock held by Bii Biosciences Limited. The Schedule 13G filed by Bii Biosciences Limited provides information as of December 31, 2022 and, consequently, the beneficial ownership of Bii Biosciences Limited may have changed between December 31, 2022 and March 15, 2023. The principal business address for Bii Biosciences Limited is One City Center, 110 Corcoran Street, Durham, North Carolina 27701.
- (7) Consists of (i) 1,005,766 shares of common stock held by the Easom Living Trust dated August 21, 2019 of which Mr. Easom is a trustee, (ii) 97,058 shares of common stock held by the C. Easom Irrevocable Trust dated October 8, 2021 of which Mr. Easom is a trustee, (iii) 97,058 shares of common stock held by the Jude Easom Irrevocable Trust dated October 8, 2021 of which Mr. Easom is a trustee, (iv) 4,907 shares of common stock held by Mr. Easom, and (v) 185,936 shares of common stock that may be acquired by Mr. Easom pursuant to the exercise of stock options within 60 days of March 15, 2023.
- (8) Consists of (i) 18,289 shares of common stock and (ii) 81,792 shares of common stock that may be acquired by Dr. Eckburg pursuant to the exercise of stock options within 60 days of March 15, 2023.
- (9) Consists of 7,483 shares of common stock that may be acquired by Mr. Aziz pursuant to the exercise of stock options within 60 days of March 15, 2023. and consists of the shares described in footnote (2) above, of which Mr. Aziz disclaims beneficial ownership of all such shares except to the extent of his pecuniary interests therein.
- (10) Consists of 10,362 shares of common stock that may be acquired by Ms. FitzPatrick pursuant to the exercise of stock options within 60 days of March 15, 2023.
- (11) Consists of (i) 22,830 shares of common stock and (ii) 17,472 of which shares of common stock that may be acquired by Dr. Marks pursuant to the exercise of stock options within 60 days of March 15, 2023, and 5,990 of which shares will continue to be subject to our repurchase right.
- (12) Consists of 27,028 shares of common stock that may be acquired by Ms. Martin pursuant to the exercise of stock options within 60 days of March 15, 2023.
- (13) Consists of 17,420 shares of common stock that may be acquired by Dr. Spigelman pursuant to the exercise of stock options within 60 days of March 15, 2023.
- (14) Consists of (i) 7,483 shares of common stock that may be acquired by Dr. Readnour pursuant to the exercise of stock options within 60 days of March 15, 2023, and (ii) 487,592 shares of common stock held by MGC Venture Partners QP 2018, LP ("MGC 2018 QP") and 417,363 shares of common stock held by MGC Venture Partners 2018, LP ("MGC 2018 LP"). MGC Venture Partners 2018 GP, LLC ("MGC 2018 GP") is the general partner of MGC 2018 LP and MGC 2018 QP. MGC 2018 GP has shared voting and shared dispositive power over the shares held by MGC 2018 LP and MGC 2018 QP. Dr. Readnour is a member of MGC 2018 QP and MGC 2018 LP and a managing partner of MGC 2018 GP and has shared voting power and shared dispositive power over the shares of common stock held by MGC 2018 LP and MGC 2018 QP. Mr. Readnour, however, disclaims beneficial ownership of such shares of common stock, except to the extent of any pecuniary interest therein. The address of each of the foregoing entities and Dr. Readnour is 3835 Cleghorn Avenue, Suite 300 Nashville, Tennessee 37215.
- (15) Consists of 27,028 shares of common stock that may be acquired by Ms. Wong pursuant to the exercise of stock options within 60 days of March 15, 2023.
- (16) Consists of (i) 505,880 shares of common stock held by Z3 Trust, of which Mr. Zakrzewski is an affiliate, (ii) 98,199 shares of common stock, and (iii) 77,028 shares of common stock that may be acquired by Mr. Zakrzewski pursuant to the exercise of stock options within 60 days of March 15, 2023.

- (17) See footnotes (7) through (16) above; also includes Lucy Day, Kevin Krause and Sanjay Chanda, Ph.D., who are executive officers but not named executive officers. Ms. Day may acquire 122,710 shares of common stock pursuant to the exercise of stock options within 60 days of March 15, 2023. Mr. Krause may acquire 119,947 shares of common stock pursuant to the exercise of stock options within 60 days of March 15, 2023. Dr. Chanda may acquire 138,623 shares of common stock pursuant to the exercise of stock options within 60 days of March 15, 2023.

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

Transactions with Related Persons

Other than compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, the following is a description of each transaction since January 1, 2021, to which we were a party, in which:

- the amounts involved exceeded or will exceed \$120,000; and
- any of our directors, nominees for director, executive officers or beneficial holders of more than 5% of any class of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

Lucy Day is our Chief Financial Officer. Ms. Day's spouse is Senior Director, IT and Operations of the Company.

Ms. Day's spouse received compensation of approximately \$300,000 in 2022, including an annual salary and incentive award commensurate with his qualifications, responsibilities, and other employees holding similar positions. He does not report directly or indirectly to Ms. Day. This relationship was ratified by the audit committee.

License Agreements

Anacor Pharmaceuticals

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 Series A Preferred Stock in November 2019, and additional shares in October 2020 in conjunction with the first and second closings of our Series A redeemable convertible preferred stock financing, respectively. 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.

Brii Biosciences

In November 2019, we 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 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.

Adjuvant Global Health

In conjunction with Adjuvant Global Health Technology Fund L.P.'s ("Adjuvant") investment in the Company's Series A redeemable convertible preferred stock financing in November 2019, the Company entered into a Global Health Agreement with Adjuvant (the "Adjuvant Agreement"), 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 Low-Middle-Income Countries (as such terms are defined by the World Bank and in the agreement). Adjuvant purchased shares of the Company's Series A redeemable convertible preferred stock in 2019 and 2020 for a total investment of \$5.0 million.

In conjunction with Adjuvant's investment in the Company's Series B redeemable convertible preferred stock financing in March 2021, the Company entered into an Amended and Restated Global Health Agreement (the "Adjuvant Amendment"). The Adjuvant Amendment expands Adjuvant's investment support to include the development of the Company's product candidate, epetraborole, for use in tuberculosis-endemic and tuberculosis-at-risk countries as defined in the agreement. Adjuvant purchased shares of the Company's Series B redeemable convertible preferred stock in 2021 for a total investment of \$7.0 million.

If we do not maintain compliance with the investment commitments under the Adjuvant Agreement and the Adjuvant Amendment (together, the "Adjuvant Agreements"), Adjuvant may be entitled to repayment for any portion of its investment that is not used for the purposes outlined in the Adjuvant Agreements. Risk of repayment under the Global Health Agreement is limited to Adjuvant's aggregate investment of \$12.0 million in our Series A and Series B redeemable convertible preferred stock in 2019, 2020 and March 2021. Adjuvant's aggregate investment of \$12.0 million has been fully utilized toward development of epetraborole, including toxicology studies, clinical trials, and manufacturing activities to the extent development of epetraborole for NTM lung disease overlaps with development of epetraborole for melioidosis, tuberculosis, and any other mutually agreed-upon products.

IPO Participation

Adjuvant purchased 166,666 shares in our IPO for an aggregate purchase price of approximately \$2.5 million. In connection with Adjuvant's investment in the Company's common stock as part of the IPO, the Company entered into an Amended and Restated Global Health Agreement dated March 24, 2022. Kabeer Aziz, a member of our board of directors, is a limited partner of Adjuvant Capital GP, L.P., which is the sole general partner of Adjuvant Global Health Technology Fund L.P. and Adjuvant Global Health Technology Fund DE, L.P.

MGC 2018 LP and MGC 2018 QP purchased 70,716 shares and 82,618 shares, respectively, in our IPO for an aggregate purchase price of approximately \$2.3 million. Rob Readnour, a member of our board of directors, is a member of MGC 2018 QP and MGC 2018 LP and a managing partner of MGC 2018 GP, which is the general partner of MGC 2018 LP and MGC 2018 QP.

Investors' Rights Agreement

We are party to an amended and restated investors' rights agreement with certain holders of our capital stock, including entities affiliated with Adjuvant, entities affiliated with Biotechnology Value Fund, entities affiliated with MGC Venture Partners, entities affiliated with RA Capital, Anacor, and Brie Biosciences. Under our investor rights agreement, certain holders of our capital stock have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing.

Indemnification Agreements

We have entered into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and our amended restated certificate of incorporation and amended and restated bylaws require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law.

Related Person Transaction Policy

Our audit committee maintains the primary responsibility for reviewing and approving or disapproving “related person transactions,” which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed \$120,000 and in which a related person has or will have a direct or indirect material interest. The charter of our audit committee will provide that our audit committee shall review and approve in advance any related person transaction.

Our related person transaction policy provides that we are not permitted to enter into any transaction that exceeds \$120,000 and in which any related person has a direct or indirect material interest without the consent of our audit committee. In approving or rejecting any such transaction, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to our audit committee, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person’s interest in the transaction.

Director Independence

Our common stock is listed on The Nasdaq Stock Market (“Nasdaq”). Under the rules of Nasdaq, independent directors must comprise a majority of a listed company’s board of directors. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Under the rules of Nasdaq, a director will only qualify as an “independent director” if, in the opinion of that company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the rules of Nasdaq, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the rules of Nasdaq, the board of directors must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company which is material to that director’s ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director and (ii) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our Board undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board has determined that none of our directors, other than Mr. Easom, have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the rules of Nasdaq. Our Board has determined that Mr. Easom, by virtue of his position as our Chief Executive Officer, is not independent under applicable rules and regulations of the SEC and the Nasdaq Listing Rules.

In making these determinations, our Board considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them. There are no family relationships among any of our directors or executive officers.

Item 14. Principal Accounting Fees and Services.

Audit and Non-Audit Fees

The following table presents fees for professional audit services rendered by PricewaterhouseCoopers LLP for the audit of the Company's annual financial statements and internal control over financial reporting for the fiscal years ended December 31, 2022 and 2021 and fees billed for audit-related, tax, and other services rendered by PricewaterhouseCoopers LLP during those periods.

	2022	2021
Audit fees ⁽¹⁾	\$ 1,025,000	\$ 1,320,000
All other fees ⁽²⁾	4,150	—
Total fees	<u>\$ 1,029,150</u>	<u>\$ 1,320,000</u>

- (1) Audit fees consist of fees billed for professional services performed by PricewaterhouseCoopers LLP for the audit of our annual financial statements, the review of interim financial statements, and related services that are normally provided in connection with registration statements.
- (2) All other fees include any fees billed that are not audit, audit related, or tax fees. These fees related to accounting research software.

All fees described above were pre-approved by our audit committee.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Pursuant to the audit committee charter and policy, the audit committee pre-approves all audit and permissible non-audit services to be provided by our independent registered public accounting firm. As part of its review, the audit committee also considers whether the categories of pre-approved services are consistent with the rules on accountant independence of the SEC and the Public Company Accounting Oversight Board.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

(1) *Financial Statements:*

Report of Independent Registered Public Accounting Firm (PCAOB ID: 238)	F-2
Balance Sheets as of December 31, 2022 and 2021	F-3
Statements of Operations and Comprehensive Loss for the years ended December 31, 2022 and 2021	F-4
Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2022 and 2021	F-5
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(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.	S-1	333-263295	3.2	March 4 2022
3.2	Amended and Restated Bylaws.	S-1	333-263295	3.4	March 4, 2022
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				
10.1#	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.	S-1	333-263295	10.3	March 4, 2022
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#	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the AN2 Therapeutics, Inc. 2022 Equity Incentive Plan.	S-1	333-263295	10.5	March 4, 2022
10.6#	AN2 Therapeutics, Inc. 2022 Employee Stock Purchase Plan.	S-1	333-263295	10.6	March 4, 2022
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
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#*	Offer Letter by and between the Registrant and Kevin Krause, dated November 19, 2019.				
10.18#*	Offer Letter by and between the Registrant and Paul Eckburg, dated April 30, 2021.				

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document**				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document**				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document**				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document**				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document**				
104	Cover Page Interactive Data File (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, 2022 and 2021; (iii) the Statements of Operations and Comprehensive Loss for the years ended December 31, 2022 and 2021; (iv) the Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2022 and 2021; (vi) the Statements of Cash Flows for the years ended December 31, 2022 and 2021; (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 29, 2023.

AN2 Therapeutics, Inc.

By: /s/ Eric Easom
Eric Easom
Chief Executive Officer and Director

By: /s/ Lucy O. Day
Lucy O. Day
Chief Financial 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
<u>/s/ Eric Easom</u> Eric Easom	Chief Executive Officer and Director (Principal Executive Officer)	March 29, 2023
<u>/s/ Lucy O. Day</u> Lucy O. Day	Chief Financial Officer (Principal Financial Officer)	March 29, 2023
<u>/s/ Michael A. Nazak</u> Michael A. Nazak	Vice President and Controller (Principal Accounting Officer)	March 29, 2023
<u>/s/ Joseph Zakrzewski</u> Joseph Zakrzewski	Chair and Director	March 29, 2023
<u>/s/ Kabeer Aziz</u> Kabeer Aziz	Director	March 29, 2023
<u>/s/ Maggie FitzPatrick</u> Maggie FitzPatrick	Director	March 29, 2023
<u>/s/ Gilbert L. Marks</u> Gilbert L. Marks	Director	March 29, 2023
<u>/s/ Patricia (Patty) Martin</u> Patricia (Patty) Martin	Director	March 29, 2023
<u>/s/ Rob Readnour</u> Rob Readnour	Director	March 29, 2023
<u>/s/ Melvin Spigelman</u> Melvin Spigelman	Director	March 29, 2023
<u>/s/ Stephanie Wong</u> Stephanie Wong	Director	March 29, 2023

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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, 2022 and 2021, and the related statements of Operations and Comprehensive Loss, of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) and of cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022 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 29, 2023

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,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 27,219	\$ 12,097
Short-term investments	68,840	46,458
Prepaid expenses and other current assets	2,509	1,551
Right-of-use asset, net	53	—
Total current assets	98,621	60,106
Deferred offering costs	—	1,724
Long-term investments	3,219	3,486
Other assets, long-term	720	—
Total assets	<u>\$ 102,560</u>	<u>\$ 65,316</u>
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 2,122	\$ 1,063
Accrued compensation	2,168	916
Accrued liabilities	2,837	1,399
Operating lease liabilities	53	—
Options subject to repurchase, short-term	6	17
Total current liabilities	7,186	3,395
Options subject to repurchase, long-term	2	13
Total liabilities	7,188	3,408
Commitments and contingencies (Note 8)		
Redeemable convertible preferred stock: \$0.00001 par value; 0 and 11,409,536 shares authorized at December 31, 2022 and 2021, respectively, 0 and 11,409,488 shares issued and outstanding at December 31, 2022 and 2021, respectively; aggregate liquidation preference \$0 and \$103,064 at December 31, 2022 and 2021, respectively	—	109,319
Stockholders' equity (deficit):		
Preferred stock, \$0.00001 par value; 10,000,000 and 0 shares authorized December 31, 2022 and 2021, respectively; no shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, \$0.00001 par value; 500,000,000 and 17,166,642 shares authorized at December 31, 2022 and 2021, respectively; 19,402,658 and 2,730,298 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	185,469	—
Accumulated other comprehensive loss	(374)	(27)
Accumulated deficit	(89,723)	(47,384)
Total stockholders' equity (deficit)	95,372	(47,411)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 102,560</u>	<u>\$ 65,316</u>

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)

	Years ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 28,511	\$ 16,156
Research and development—related party	1,000	750
General and administrative	12,751	4,668
Total operating expenses	<u>42,262</u>	<u>21,574</u>
Loss from operations	(42,262)	(21,574)
Interest income	1,351	69
Other expense	(45)	(38)
Net loss	(40,956)	(21,543)
Accretion to redemption value and cumulative dividends on preferred stock	(1,820)	(6,515)
Net loss attributable to common stockholders	<u>\$ (42,776)</u>	<u>\$ (28,058)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (2.79)</u>	<u>\$ (10.64)</u>
Weighted-average number of shares used in computing net loss per share, basic and diluted	<u>15,340,134</u>	<u>2,638,197</u>
Other comprehensive loss:		
Unrealized loss on investments	(347)	(27)
Comprehensive loss	<u>\$ (41,303)</u>	<u>\$ (21,570)</u>

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

AN2 THERAPEUTICS, INC.
STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share and per share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss		Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balances at December 31, 2020	6,076,196	23,070	2,707,468	—	—	—	—	(20,319)	(20,319)
Issuance of Series B redeemable convertible preferred stock at \$15.00 per share for cash, net of issuance costs of \$266	5,333,292	79,734	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	22,830	—	—	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	19	—	—	—	19
Stock-based compensation	—	—	—	—	974	—	—	—	974
Accretion to redemption value and cumulative dividends on preferred stock	—	—	—	—	—	—	—	—	—
Unrealized loss on available-for-sale investments	—	6,515	—	—	(993)	—	—	(5,522)	(6,515)
Net loss	—	—	—	—	—	(27)	—	—	(27)
Balances at December 31, 2021	11,409,488	\$ 109,319	2,730,298	\$ —	\$ —	\$ —	(21,543)	\$ (47,384)	(21,543)
Conversion of convertible preferred stock into common stock	(11,409,488)	(111,139)	11,409,488	—	111,139	—	—	—	(47,411)
Issuance of common stock upon initial public offering, net of underwriters' commission and offering costs of \$8.1 million	—	—	—	—	—	—	—	—	111,139
Issuance of common stock upon exercise of the underwriter's option to purchase common stock in connection with the initial public offering, net of underwriters' commission and offering costs of \$0.8 million	—	—	4,600,000	—	60,836	—	—	—	60,836
Vesting of early exercised stock options	—	—	690,000	—	9,530	—	—	—	9,530
Repurchase of early exercised stock options	—	—	—	—	21	—	—	—	21
Stock-based compensation	—	—	(27,128)	—	(11)	—	—	—	(11)
Accretion to redemption value and cumulative dividends on preferred stock	—	—	—	—	4,391	—	—	—	4,391
Unrealized loss on available-for-sale investments	—	1,820	—	—	(437)	—	—	(1,383)	(1,820)
Net loss	—	—	—	—	—	(347)	—	—	(347)
Balances at December 31, 2022	—	\$ —	19,402,658	\$ —	\$ 185,469	\$ (374)	\$ (40,956)	\$ (89,723)	\$ (40,956)
									95,372

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

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

	Year ended December 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (40,956)	\$ (21,543)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	4,391	974
Non-cash operating lease expense	77	—
Net amortization (accretion) of premium (discount) on investments	(692)	53
Changes in operating assets and liabilities:		
Increase in prepaid expenses and other current assets	(958)	(1,387)
Increase in other assets	(720)	—
Increase in accounts payable	2,497	417
Increase in accrued compensation	1,252	490
Increase in accrued liabilities	1,724	512
Decrease in operating lease liabilities	(77)	—
Net cash used in operating activities	(33,462)	(20,484)
Cash flows from investing activities		
Purchases of investments	(93,836)	(77,274)
Maturities of investments	72,065	27,250
Net cash used in investing activities	(21,771)	(50,024)
Cash flows from financing activities		
Proceeds from issuance of common stock from the initial public offering, net of underwriting discounts, commissions and offering expenses	70,366	—
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	79,734
Payments of issuance costs for initial public offering	—	(1,210)
Proceeds from exercise of stock options	—	11
Repurchase of early exercised stock options	(11)	—
Net cash provided by financing activities	70,355	78,535
Net increase in cash	15,122	8,027
Cash at beginning of period	12,097	4,070
Cash at end of period	\$ 27,219	\$ 12,097
Supplemental disclosure of noncash financing items		
Conversion of redeemable convertible preferred stock into common stock	\$ 111,139	\$ —
Accretion to redemption value and cumulative dividends on preferred stock	1,820	6,515
Issuance costs for initial public offering included in accounts payable and accrued liabilities	—	514

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

AN2 Therapeutics, Inc.
Notes to Financial Statements

Note 1. Organization and Description of the Business

Description of Business

AN2 Therapeutics, Inc. (the “Company”) is a clinical-stage biopharmaceutical company focused on developing treatments for rare, chronic, and serious infectious diseases with high unmet needs. The Company's initial product candidate, epetraborole, is under development in a pivotal Phase 2/3 clinical trial as a once-daily, oral treatment for patients with non-tuberculous mycobacterial (NTM) lung disease with an initial focus on treatment-refractory *Mycobacterium avium* complex (MAC) lung disease. 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, business planning, 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 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.

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”).

For all periods presented, shares of common stock and then existing redeemable convertible preferred stock and per share amounts have been adjusted on a retroactive basis to reflect our 2.352936-for-1 forward stock split, which was effected on March 18, 2022. The stock split did not change the par value of the common stock and redeemable convertible preferred stock or the authorized number of shares of common stock and redeemable convertible preferred stock.

Risks and Uncertainties

Liquidity

Prior to the Company's IPO in March 2022, 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, 2022 and 2021, the Company incurred a net loss of \$41.0 million and \$21.5 million, respectively, and had cash flows used in operating activities of \$33.5 million and \$20.5 million, respectively. The Company has an accumulated deficit of \$89.7 million and \$47.4 million as of December 31, 2022 and 2021, 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 candidate currently in development.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

As of December 31, 2022, the Company had cash, cash equivalents and investments of \$99.3 million. Management believes that its cash, cash equivalents and investments as of December 31, 2022 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, registration and pre-registration 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.

Other Risks and Uncertainties

The Company is subject to a number of risks similar to those of other clinical-stage biopharmaceutical companies, including, but not limited to: ability to timely enroll and complete clinical trials, ability to replicate preclinical trial results in later-stage clinical trials, dependence on key individuals, the need to develop commercially viable therapeutics, competition from other companies, many of which are larger and better capitalized, protection of intellectual property rights, litigation or claims against the Company based on intellectual property rights, regulatory clearance, market acceptance of the Company's products and the need to obtain adequate additional financing to fund the development of its products.

In March 2020, the World Health Organization declared the global novel coronavirus disease ("COVID-19") outbreak a pandemic. To date, the Company's business has not been materially impacted by the COVID-19 pandemic. However, the Company has experienced certain slowing of its preclinical and clinical trials and cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on its financial condition and operations, including ongoing and planned preclinical and nonclinical studies, clinical trials and clinical trial material manufacturing. The impact of the COVID-19 pandemic on the financial performance of the Company will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of COVID-19 on the financial markets and the overall economy are highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be adversely affected.

In February 2022, Russia commenced a military invasion of Ukraine. The ongoing geopolitical turmoil and continuing military action in the region, together with widening sanctions imposed on Russia, have caused disruptions in the global economy, related to trade and shipping, and increased costs of transportation. The duration and impact of the conflict between Russia and Ukraine is highly unpredictable and the extent to which the conflict may impact certain of the Company's clinical development and regulatory efforts remains uncertain. While the Company does not currently conduct any trials in Russia or Ukraine, any disruptions or increased costs related to the shipping of supplies and drug product necessary to conduct the Company's trials could negatively impact the Company's liquidity and cash flows.

In addition, global economic and business activities continue to face widespread macroeconomic uncertainties, including labor shortages and supply chain disruptions, bank failures, inflation and monetary supply shifts, as well as recession risks, which may continue for an extended period, and which could result in additional costs and delays in the Company's clinical development and regulatory efforts.

Segments

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on a company-wide basis for purposes of allocating resources and assessing financial performance.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

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.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly related to the Company's equity financings, including its IPO, until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds received as a result of the financing. The Company capitalized certain legal, accounting and other third-party fees that were directly related to the Company's IPO. After the completion of the IPO in March 2022, the total deferred offering costs of \$3.3 million were offset against the proceeds from the IPO and reclassified to additional paid-in capital in the accompanying balance sheets. At December 31, 2022 and 2021, deferred offering costs totaling \$0 and \$1.7 million, respectively, were included as non-current assets in the accompanying balance sheet.

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, and includes 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.

Redeemable Convertible Preferred Stock

The Company recorded redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs. The carrying value of the redeemable convertible preferred stock was accreted to its redemption value. Immediately prior to the closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock were converted into shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital. There were no shares of redeemable convertible preferred stock outstanding as of December 31, 2022.

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.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

The valuation model used for calculating the fair value of stock options for stock 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 elected to apply the practical expedient for private companies and used the simplified method to determine the awards' 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.

Fair Value of Common Stock

Prior to the Company's IPO, the absence of an active market for the Company's common stock required the Company's board of directors ("Board") to determine the fair value of its common stock for purposes of granting stock options. The fair value of the Company's common stock was determined by the Company's Board with assistance from management and an independent third-party valuation firm. Management's approach to estimating the fair value of the Company's common stock was consistent with the methods outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately-Held- Company Equity Securities Issued as Compensation*. Determining the best estimated fair value of the Company's common stock requires significant judgement and management considers several factors, including the Company's stage of development, equity market conditions affecting comparable public companies, significant milestones and progress in research and development efforts. Since the completion of its IPO, the Company uses its stock price as traded on the Nasdaq Global Select Market to determine the fair value of its common stock.

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, 2022 and 2021, the Company had cash and cash equivalents of \$27.2 million and \$12.1 million, respectively.

Investments

Investments consist of U.S. Treasuries, asset-backed securities, corporate debt securities and corporate commercial paper. 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.

Unrealized gains and losses on available-for-sale investments are reported in accumulated other comprehensive gain (loss) as a separate component of stockholders' equity (deficit). Investments are regularly reviewed for other-than-temporary declines in fair value. The review includes consideration of the cause of impairment, including the creditworthiness of the security issuers, the number of investments in an unrealized loss position, the severity and duration of the unrealized losses, and whether it is more likely than not that the Company will be required to sell the investments before the recovery of their amortized cost basis. The cost of investments sold, if any, is based on the specific identification method. To date, the Company has not recorded any impairment charges on its investments related to other-than-temporary declines in market value. As of December 31, 2022 and 2021, the Company had investments of \$72.1 million and \$49.9 million, respectively.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

Cloud Computing Arrangements

The Company incurs costs to implement cloud computing arrangements (“CCA”) that are hosted by third-party vendors. Implementation costs incurred during the application development stage are considered for capitalization until the software is ready for its intended use. Once capitalized, these costs are then amortized on a straight-line basis over the term of the associated hosting arrangement and are recognized as an operating expense within the statements of operations and comprehensive income (loss). As of December 31, 2022, the Company has not capitalized any CCA implementation costs or amortized any such costs.

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 may at times exceed federally insured limits, but minimal credit risk exists. The Company invests its cash equivalents in highly rated money market funds. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds.

The Company is exposed to credit risk in the event of a default by the financial institution 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, 2022, 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 Infection 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, under 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).

Comprehensive Loss

Comprehensive loss includes net loss and certain changes in stockholders’ equity (deficit) 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, 2022 and 2021, the Company had \$0.3 million and \$0.03 million of net unrealized loss on available-for-sale investments, respectively.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

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, redeemable convertible preferred stock, stock options, common stock subject to repurchase related to unvested early exercise of stock options 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 as the redeemable convertible preferred stock is considered a participating security because it participates in dividends with common stock, and is accreted to redemption. 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 all series of redeemable convertible preferred stock and 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.

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. 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 July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements ("ASU 2018-11"). ASU 2018-11 provided an alternative method in addition to the modified retrospective transition method for ASU No. 2016-02, Leases: Amendments to the FASB Accounting Standards Codification ("ASU 2016-02"), issued in February 2016. Under ASU 2018-11, an entity may elect to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Under ASU 2016-02, a lease is required to recognize assets and liabilities with lease terms of more than twelve months. ASU 2016-02 is effective for nonpublic business entities and public entities eligible to be Smaller Reporting Companies for fiscal years beginning after December 15, 2021.

The Company adopted the new standard on January 1, 2022 using the modified retrospective approach. The Company has elected to apply the transition method that allows companies to continue applying the guidance under the lease standard in effect at that time in the comparative periods presented in the financial statements and recognize a cumulative-effect adjustment to the opening balance of accumulated deficit on the date of adoption. The Company has elected to combine lease components (e.g., fixed rent payments) with non-lease components (e.g., common-area maintenance costs) on its facility and clinical research organization ("CRO") embedded lease asset classes. The Company also elected the "package of practical expedients", which permits the Company not to reassess under the new standard the Company's prior conclusions about lease identification, lease classification and initial direct costs. The Company also elected the short-term lease practical expedients allowed under the standard. Lastly, the Company did not elect the practical expedient allowing the use-of-hindsight which would require the Company to reassess the lease term of its leases based on all facts and circumstances through the effective date.

Results for reporting periods beginning after January 1, 2022 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. Upon adoption of the new lease standard, on January 1, 2022, the Company capitalized operating lease right-of-use (ROU) assets of \$0.05 million and \$0.05 million of operating lease liabilities, within the balance sheets upon adoption.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

In November 2021, the FASB issued ASU No. 2021-10, Government Assistance (Topic 832) Disclosures by Business Entities about Government Assistance. Current U.S. GAAP has no specific authoritative guidance on the accounting for, or the disclosure of, government assistance received by business entities. The amendments in this update improve financial reporting by requiring disclosures that increase the transparency of transactions with a government accounted for by applying a grant or contribution accounting model by analogy, including the types of transactions, the accounting for those transactions, and the effect of those transactions on an entity's financial statements. The amendments in this update require the following annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy, including: (1) information about the nature of the transactions and the related accounting policy used to account for the transactions; (2) the line items on the balance sheet and income statement that are affected by the transactions, and the amounts applicable to each financial statement line item; and (3) the significant terms and conditions of the transactions, including commitments and contingencies. The amendments in this update are effective for all entities within their scope for financial statements issued for annual periods beginning after December 15, 2021. Early application of the amendments is permitted. The Company adopted this update during the year ended December 31, 2022 and accounted for the NIAID contract in accordance with this update, which did not have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU 2018-15, "Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (a consensus of the FASB Emerging Issues Task Force)". This update is intended to guide entities in evaluating the accounting for fees paid by a customer in a cloud computing arrangement by providing guidance for determining when the arrangement includes a software license. This standard was effective for financial statements issued by public companies for annual and interim periods beginning after December 15, 2019, and effective for financial statements issued by non-public entities for annual periods beginning after December 15, 2020. The Company adopted this standard beginning July 1, 2022, noting that this standard was applied prospectively. Adoption of this standard did not have a material impact on the Company's financial statements.

Recent Accounting Pronouncements Not Yet Adopted

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. 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.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"), which requires an entity to utilize a new impairment model known as the current expected credit loss ("CECL") model to estimate its lifetime "expected credit loss" and record an allowance that, when deducted from the amortized cost basis of the financial assets and certain other instruments, including but not limited to available-for-sale debt securities. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. ASU 2016-13 requires a cumulative effect adjustment to the balance sheet as of the beginning of the first reporting period in which the guidance is effective. In November 2019, the FASB issued ASU 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates, which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022 for SEC reporting companies that are smaller reporting companies such as the Company. The Company is currently evaluating the impact of the adoption of ASU 2016-13 on its financial statements, and will consider the extended transition period available to "emerging growth" companies.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

Note 3. Fair Value Measurements

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, short- and long-term investments, prepaid expenses, accounts payable, and accrued liabilities. The carrying amounts of the Company's financial instruments, other than cash equivalents, short- and long-term 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, 2022					
	Level	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Cash equivalents:					
Money market funds	Level 1	\$ 10,152	\$ —	\$ —	\$ 10,152
Short-term investments:					
U.S. Treasury securities	Level 1	29,381	—	(213)	29,168
Commercial paper	Level 2	27,701	2	(82)	27,621
U.S. Government agency securities	Level 2	12,126	4	(79)	12,051
Long-term investments:					
U.S. Treasury securities	Level 1	1,224	—	(1)	1,223
U.S. Government agency securities	Level 2	2,001	—	(5)	1,996
Total		<u>\$ 82,585</u>	<u>\$ 6</u>	<u>\$ (380)</u>	<u>\$ 82,211</u>

December 31, 2021					
	Level	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Cash equivalents:					
Money market funds	Level 1	\$ 3,567	\$ —	\$ —	\$ 3,567
Commercial paper	Level 2	2,999	—	—	2,999
Corporate debt securities	Level 2	1,501	—	—	1,501
Short-term investments:					
U.S. Treasury securities	Level 1	4,500	—	(11)	4,489
Commercial paper	Level 2	33,716	4	(5)	33,715
Asset-backed securities	Level 2	8,261	—	(7)	8,254
Long-term investments:					
U.S. Treasury securities	Level 1	3,494	—	(8)	3,486
Total		<u>\$ 58,038</u>	<u>\$ 4</u>	<u>\$ (31)</u>	<u>\$ 58,011</u>

For the years ended December 31, 2022 and 2021, there were no other-than-temporary impairment charges recognized in accumulated other comprehensive income.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

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 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, 2022.

As of December 31, 2022, 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, 2022 and 2021, 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.

Note 4. Funding Arrangements

NIAID Contract

In September 2022, the Company received a cost-reimbursed contract award from the NIAID to support preclinical, Phase 1 studies and other activities to enable the advancement of epetaborole into late-stage development for acute systemic melioidosis and other biothreat pathogens. The Company can receive up to \$17.8 million in funding over a total term of 48 months, consisting of a base period and seven option periods. As of December 31, 2022, funding for an 18-month base period totaling \$4.3 million has been committed. The Company did not recognize any income under this agreement during the year ended December 31, 2022.

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.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

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 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.

During the years ended December 31, 2022 and 2021, the Company recorded \$1.0 million and \$0.8 million in research and development expense—related party, respectively, to Anacor upon the achievement of development milestones.

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. Leases

In May 2021, the Company entered into an operating lease agreement for its principal office in Menlo Park, California. In September 2021, the lease was amended to extend the term to expire in August 2022. In July 2022, the lease was further amended to exercise a renewal option and extend the term to expire in August 2023. Under the lease agreement, the Company has two additional 12-month renewal options through August 2025.

The Company has not entered into any finance lease agreements as of December 31, 2022.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

The following table summarizes maturities of lease liabilities and the reconciliation of lease liabilities as of December 31, 2022 (in thousands):

	Operating Leases
2023	\$ 54
2024 and thereafter	—
Total future undiscounted lease payments	54
Less: imputed interest	(1)
Total lease liabilities	<u>\$ 53</u>

The following table summarizes total lease expense during the year ended December 31, 2022 (in thousands):

	Statements of Operations and Comprehensive Loss Classification	Year Ended December 31, 2022
Operating lease expense	Operating expenses	\$ 80
Short-term lease expense	Operating expenses	72
Total lease expense		<u>\$ 152</u>

Rent expense was insignificant during the year ended December 31, 2021.

The Company paid \$0.08 million in operating cash flows from operating leases for amounts included in the measurement of liabilities during the year ended December 31, 2022.

As of December 31, 2022, the weighted-average remaining lease term and discount rate for operating leases was 0.67 years and 5.1%, respectively.

Note 7. Balance Sheet Components

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2022	2021
Accrued research and development-related expenses	\$ 2,517	\$ 495
Accrued research and development-related expenses—related party	—	500
Accrued professional services expenses	198	50
Accrued offering costs	—	313
Other	122	41
Total accrued liabilities	<u>\$ 2,837</u>	<u>\$ 1,399</u>

Note 8. 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, 2022 and 2021, and no material legal proceedings are currently pending or threatened.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

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's Series A redeemable convertible preferred stock financing in November 2019, 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 Low-Middle-Income Countries (as such terms are defined by the World Bank and in the agreement). In 2019 and 2020, Adjuvant purchased Series A redeemable convertible preferred stock for a total of \$5.0 million.

Adjuvant's investment supports the development of the Company's product candidate, epetraborole, for use in melioidosis-endemic and melioidosis-at-risk countries as defined in the agreement. These global access commitments became effective as of the Series A redeemable convertible preferred stock financing closing date and 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. If the Company does not maintain compliance with these non-financial covenants, 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. As of December 31, 2020, the \$5.0 million aggregate proceeds from Adjuvant's Series A investment have been fully utilized to support the epetraborole development program, which overlaps with the melioidosis development activities for the global health programs.

In conjunction with Adjuvant's investment in the Company's Series B redeemable convertible preferred stock financing in March 2021, the Company entered into an Amended and Restated Global Health Agreement (the "Adjuvant Amendment"). The Adjuvant Amendment expands Adjuvant's investment support to include the development of the Company's product candidate, epetraborole, for use in tuberculosis-endemic and tuberculosis-at-risk countries as defined in the agreement. Adjuvant purchased the Company's Series B redeemable convertible preferred stock in 2021 for a total investment of \$7.0 million, which is subject to Adjuvant's right of repayment should the Company not utilize the proceeds from Adjuvant's investment towards the agreed-upon purpose. As of December 31, 2021, the \$7.0 million proceeds from Adjuvant's Series B investment were fully utilized to support the epetraborole development program, which overlaps with the melioidosis and other global health development programs.

In connection with Adjuvant's investment in the Company's common stock as part of the IPO, the Company entered into an Amended and Restated Global Health Agreement dated March 24, 2022 (the "Adjuvant IPO Amendment"). As part of the 2022 Adjuvant Amendment, Adjuvant purchased 166,666 shares of the Company's common stock in March 2022 for a total additional investment of \$2.5 million, which is subject to Adjuvant's right of repayment should the Company not utilize the proceeds from Adjuvant's investment towards the agreed-upon purpose. The Company has complied with all applicable covenants as of December 31, 2022. As of December 31, 2022, the \$2.5 million of proceeds from Adjuvant's IPO investment have been fully utilized to support the epetraborole development program, which overlaps with the melioidosis and other global health development programs.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

Note 9. 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.

Shares of common stock reserved for future issuance, on an as-if-converted basis, as of December 31, 2022 and 2021, consists of the following:

	December 31,	
	2022	2021
Series A redeemable convertible preferred stock	—	6,076,196
Series B redeemable convertible preferred stock	—	5,333,292
Stock options, issued and outstanding	2,796,241	1,589,120
Stock options, authorized for future issuance	1,627,680	937,673
ESPP, authorized for future issuance	187,000	—
Total	<u>4,610,921</u>	<u>13,936,281</u>

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, 2022 and 2021.

Redeemable Convertible Preferred Stock

Immediately prior to the closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock converted into 11,409,488 shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital. There were no shares of redeemable convertible preferred stock outstanding as of December 31, 2022.

At December 31, 2021, redeemable convertible preferred stock consisted of the following (in thousands, except share and per share amounts):

	Shares Authorized	Shares Issued and Outstanding	Issuance Price Per Share	Carrying Value	Liquidation Preference
Series A	6,076,228	6,076,196	\$ 2.55	\$ 24,308	\$ 17,787
Series B	5,333,308	5,333,292	\$ 15.00	85,011	85,277
	<u>11,409,536</u>	<u>11,409,488</u>		<u>\$ 109,319</u>	<u>\$ 103,064</u>

Note 10. 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, 2022, no stock appreciation rights, restricted stock awards, restricted stock unit awards or performance awards were issued under the 2022 Plan.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

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 underlying outstanding stock awards granted 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 maximum 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 Board no later than December 31 of the immediately preceding year. The number of shares of the Company's common stock that are available to be issued on the exercise of stock options under the 2022 Plan is 13,271,760 shares.

Since the date of incorporation and through December 31, 2022, the Company issued stock options to its employees, directors and consultants. As of December 31, 2022, 1,627,680 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.

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, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development expenses	\$ 1,688	\$ 429
General and administrative expenses	2,703	545
Total	<u>\$ 4,391</u>	<u>\$ 974</u>

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.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

- Expected Volatility—since the Company recently became a public company and has only a limited trading history for its common stock, the expected volatility was estimated 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.

For options granted to non-employee consultants, the fair value of these options is also remeasured using the Black-Scholes option pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected term, which is assumed to be the remaining contractual term of the option.

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

	Year Ended December 31, 2022	Year Ended December 31, 2021
Expected term	5.94 years	5.99 years
Expected volatility	83.4%	85.8%
Risk-free interest rate	3.07%	1.08%
Expected dividend yield	—	—

Stock Option Plan Activity

A summary of the stock plan activity is as follows:

	Total Options Outstanding	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2021	1,589,120	\$ 5.95	9.27	\$ 5,482
Granted	1,238,953	15.40		
Exercised	—	—		
Forfeited	(31,832)	6.60		
Outstanding at December 31, 2022	<u>2,796,241</u>	\$ 10.13	8.81	\$ 5,793
Exercisable as of December 31, 2022	<u>987,857</u>	\$ 7.04	8.30	\$ 3,865

As of December 31, 2022, there was unrecognized stock-based compensation expense of \$15.0 million related to unvested stock options which the Company expects to recognize over a weighted-average period of 2.8 years.

Weighted-average grant-date fair value of the options granted during the year ended December 31, 2022 was \$11.03 per share. No options were exercised during the year ended December 31, 2022.

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.

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Notes to Financial Statements — Continued

As of December 31, 2022, there were 19,778 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, 2022, 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. As of December 31, 2022, 187,000 shares of common stock remained available for issuance under the ESPP.

The Company began recording stock-based compensation expense for its ESPP on October 1, 2022. During the year ended December 31, 2022, the Company recognized \$0.1 million in stock-based compensation expense related to the ESPP.

Note 11. Income Taxes

The Company is liable for income taxes in the United States. For the years ended December 31, 2022 and 2021, 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,	
	2022	2021
Federal tax benefit at statutory rate	\$ (8,601)	\$ (4,524)
State tax benefit at statutory rate, net of federal tax benefit	(3,053)	(1,377)
Change in valuation allowance	12,347	5,942
Research and development tax credits	(988)	(360)
Other	295	319
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>

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 \$12.3 million from December 31, 2021 to December 31, 2022 due to generation of current year net operating losses and research and development credits claimed.

AN2 Therapeutics, Inc.
Notes to Financial Statements — Continued

Deferred income taxes reflect the net tax effects of loss and 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 follow (in thousands):

	December 31,	
	2022	2021
Deferred tax assets		
Net operating loss carryforwards	\$ 13,709	\$ 8,811
Intangible assets	5,337	—
Tax credit carryforwards	1,836	561
Other	889	52
Gross deferred tax assets	21,771	9,424
Valuation allowance	(21,771)	(9,424)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2022, the Company had \$43.2 million of federal and \$66.3 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 \$1.3 million and \$0.6 million, respectively. The federal tax credit carryforwards will begin to 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, 2022 and 2021, the Company has unrecognized tax benefits of \$0.8 million and \$0.4 million, respectively. As of December 31, 2022, 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, 2022 and 2021 was as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Balance at beginning of year	\$ 445	\$ —
Additions related to prior year positions	—	314
Additions related to current year positions	338	131
Balance at end of year	<u>\$ 783</u>	<u>\$ 445</u>

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, 2022.

The Company files income tax returns in the U.S. federal jurisdiction and California state jurisdiction. The Company is not currently under audit by the Internal Revenue Service or other similar state or local authorities. All tax years of the Company remain open to examination by major taxing jurisdictions to which the Company is subject.

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Notes to Financial Statements — Continued

Note 12. 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,	
	2022	2021
Numerator:		
Net loss	\$ (40,956)	\$ (21,543)
Add accretion to redemption value and cumulative dividends on preferred stock	(1,820)	(6,515)
Net loss attributable to common stockholders	<u>\$ (42,776)</u>	<u>\$ (28,058)</u>
Denominator:		
Weighted-average common shares outstanding used to calculate net loss per share attributable to common stockholders, basic and diluted	15,340,134	2,638,197
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (2.79)</u>	<u>\$ (10.64)</u>

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,	
	2022	2021
Series A redeemable convertible preferred stock	—	6,076,196
Series B redeemable convertible preferred stock	—	5,333,292
Options issued and outstanding	2,796,241	1,589,120
Early exercised common stock subject to future vesting	19,778	71,340
Total	<u>2,816,019</u>	<u>13,069,948</u>

Note 13. Related Party Transactions

In the year ended December 31, 2022, the Company paid \$1.5 million for two development milestones to Anacor. Of this amount, a \$0.5 million payment was recognized as expense in 2021 and was included as accrued expenses in the accompanying balance sheet at December 31, 2021.

In connection with Adjuvant's investment in the Company's common stock as part of the IPO, the Company entered into the 2022 Adjuvant Amendment. As part of the 2022 Adjuvant Amendment, Adjuvant purchased 166,666 shares of the Company's common stock in 2022 for a total additional investment of \$2.5 million, which is subject to Adjuvant's right of repayment should the Company not utilize the proceeds from Adjuvant's investment towards the agreed-upon purpose. As of December 31, 2022, the \$2.5 million of proceeds from Adjuvant's IPO investment have been fully utilized to support the epetraborole development program, which overlaps with the melioidosis and other global health development programs (see Note 8—Commitments and Contingencies).

Note 14. Defined Contribution Plan

The Company began sponsoring a 401(k) Plan in 2019 that stipulates that eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations, on a pretax basis. During the years ended December 31, 2022 and 2021, the Company did not make a matching contribution.

