As confidentially submitted to the Securities and Exchange Commission on January 19, 2022.

This amended draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

AN2 Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**82-0606654**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

AN2 Therapeutics, Inc.
1800 El Camino Real, Suite D
Menlo Park, California 94027
(650) 331-9090
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Eric Easom
Chief Executive Officer
1800 El Camino Real, Suite D
Menlo Park, California 94027
(650) 331-9090
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Josh Seidenfeld **Sally Kay** **Anitha Anne** **Cooley LLP** **3175 Hanover Street** **Palo Alto, California 94304** **(650) 843-5000**	**Lucy Day** **Chief Financial Officer** **1800 El Camino Real, Suite D** **Menlo Park, California 94027** **(650) 331-9090**	**Emily Roberts** **Davis Polk & Wardwell LLP** **1600 El Camino Real** **Menlo Park, California 94025** **(650) 752-2000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common stock, par value $0.00001 per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended. Includes the aggregate offering price of any additional shares that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Prospectus (Subject to Completion) **Dated , 2022**

Shares

Common Stock

This is an initial public offering of shares of common stock of AN2 Therapeutics, Inc. We are offering shares of our common stock.

Prior to this offering, there has been no public market for our common stock. We currently expect that the initial public offering price will be between $ and $ per share of common stock.

We intend to apply to list our common stock on The Nasdaq Global Market under the symbol "ANTX."

We are an "emerging growth company" as defined in the Jumpstart Our Business Act of 2012 and, as such, we have elected to comply with certain reduced reporting requirements for this prospectus and may elect to do so in future filings.

Investing in our common stock involves a high degree of risk. See the section titled "Risk Factors" beginning on page 14.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	*Total*
Public offering price	**$**	**$**
Underwriting discounts and commissions(1)	**$**	**$**
Proceeds to AN2 Therapeutics, Inc., before expenses	**$**	**$**

(1) See the section titled "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional shares of our common stock at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on , 2022.

Cowen **SVB Leerink** **Evercore ISI**

Oppenheimer & Co.

Prospectus dated , 2022

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Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this entire prospectus, including the information under the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to "AN2 Therapeutics," "AN2," the "Company," "we," "us," and "our" refer to AN2 Therapeutics, Inc.

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 chronic non-tuberculous mycobacterial, or NTM, 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. We have completed six dosing cohorts of a double-blind, placebo-controlled Phase 1b dose-ranging study of epetraborole administered orally for 28 days in healthy volunteers in Australia, with a last food-effect cohort remaining to be completed, and completed two nonclinical chronic toxicology studies (6-month rat and 9-month non-human primates), which will inform dose selection for our Phase 2/3 clinical trial and may inform dose selection for any additional clinical trials in NTM patients. A Phase 2/3 pivotal clinical trial design in treatment-refractory *Mycobacterium avium* complex, or MAC, lung disease, which is the most common type of NTM lung disease and which we believe has the potential to be sufficient for regulatory approval in the United States, is under review with the U.S. Food and Drug Administration, or FDA. We recently received clearance of our Investigational New Drug, or IND, application by the FDA, and plan to initiate patient enrollment in our Phase 2/3 clinical trial in the first half of 2022 with topline results for the Phase 2 part of the trial anticipated in the middle of 2023 and the Phase 3 part of the trial anticipated in the middle of 2024. We also recently received Fast Track designation by the FDA to investigate epetraborole for treatment-refractory MAC lung disease. Epetraborole has also recently been designated as a Qualified Infectious Disease Product, or QIDP, for treatment-refractory MAC lung disease by the FDA. 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.

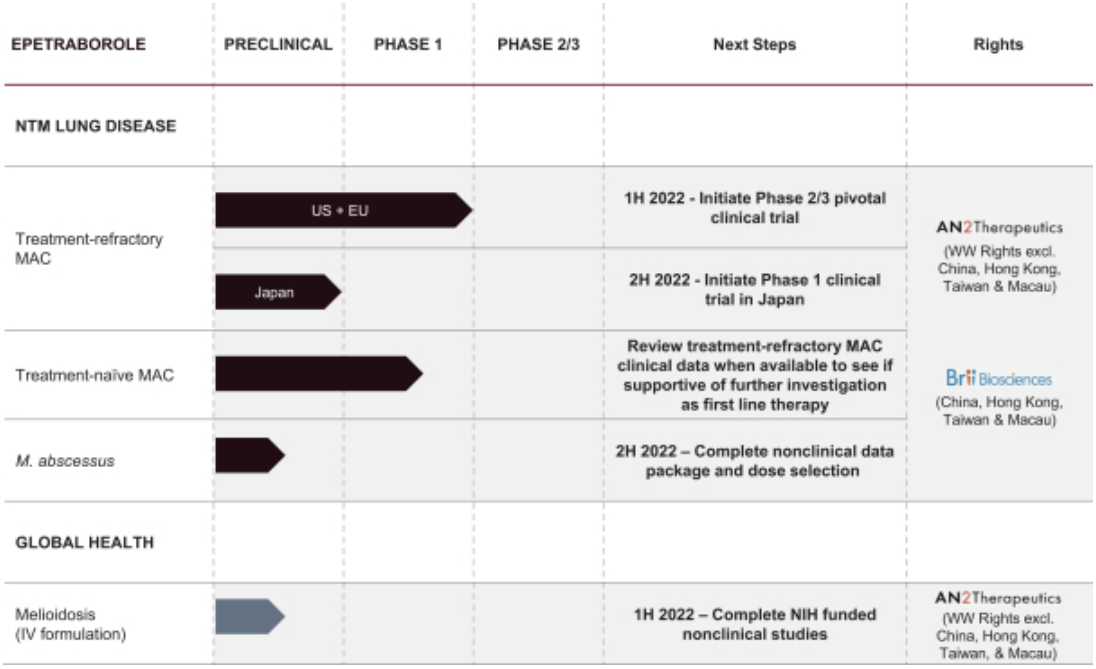
Our Pipeline

We are initially focused on advancing our first product candidate, epetraborole, to commercialization in NTM lung disease. We are developing epetraborole to treat MAC lung disease, which accounts for approximately 80% of NTM lung disease. We have in-licensed the exclusive worldwide development and commercialization rights for epetraborole from Anacor Pharmaceuticals, Inc., or Anacor, acquired by Pfizer Inc., or Pfizer, in 2016.

In addition to our development and commercial endeavors in NTM lung disease, we intend to develop epetraborole for global health initiatives, including melioidosis, using non-dilutive funding, which we plan to obtain from sources such as public and private agencies and foundations. We have

entered into an Amended and Restated Global Health Agreement, or the Global Health Agreement, with Adjuvant Global Health Technology Fund L.P. and Adjuvant Global Health Technology Fund DE L.P., or together, Adjuvant, in connection with Adjuvant's investment of $12.0 million in our Series A and Series B redeemable convertible preferred stock financings. Pursuant to the Global Health Agreement, we must use reasonably diligent endeavors to develop epetraborole for melioidosis, tuberculosis, and any other mutually agreed-upon products for at-risk developing countries. We have entered into a research agreement with the National Institutes of Health to further early development and dose selection of epetraborole in melioidosis using the in vitro hollow-fiber studies. These studies are being conducted at no cost to us. We believe partnerships like this provide substantial technical and capital resources to advance the melioidosis program and provide material benefits to our company and to our NTM program as a whole.

The below table summarizes our development plans for epetraborole:



Our AN2 Drug Discovery Platform

Our core technology approach is based on the use of boron chemistry for our drug research and development initiatives. Boron has both a distinctive 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. Boron chemistry has proven to be a highly productive technology leading to the discovery of many promising drugs, particularly focused in infectious diseases. Pioneering work at Anacor led to the generation of a class of boron compounds including two FDA-approved therapies, Kerydin and Eucrisa. Our founders consist of former leaders at Anacor, including an inventor of epetraborole and a leading infectious disease expert.

We are also actively pursuing the identification of additional antimicrobial product candidates that leverage our boron chemistry capabilities. Once identified, we plan to develop these candidates in

NTM lung disease and other rare and chronic infectious diseases. We are also selectively evaluating in-licensing opportunities of development-stage candidates that have the potential to address rare and chronic infectious diseases consistent with our corporate strategy.

Our Market Opportunity

We are developing oral epetraborole for the treatment of NTM lung disease, a rare, chronic, and progressive infectious disease caused by bacteria known as mycobacteria that lead 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.

There are an estimated 200,000 patients with NTM lung disease in the United States; however, 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 incidence of NTM lung disease is increasing in the U.S. 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, or 15,000 patients, have treatment-refractory MAC lung disease. There are approximately 20,000 total NTM patients in Europe, of which approximately 5,600 are estimated to have treatment-refractory MAC lung disease.

There is only one FDA-approved therapy for treatment-refractory MAC lung disease: Arikayce, an inhaled liposomal formulation of amikacin. In a clinical trial, the addition of Arikayce to standard of care combination antibiotic therapy resulted in the resolution of MAC infection in only 29% of patients, leaving more than 70% of treatment-refractory patients with limited or no treatment options. Furthermore, Arikayce has significant tolerability and safety issues, resulting in a boxed warning for risk of increased respiratory adverse reactions, and other warnings and precautions including ototoxicity, a known class effect with aminoglycosides, and other safety findings. Between 20.3% and 33.5% of patients treated with Arikayce in clinical trials discontinued treatment. Despite these shortcomings, Insmed reported net sales of Arikayce of over $160 million in the United States in 2020, only its second year on the market. We believe improved treatment of NTM lung disease will require an efficacious, safe, and well-tolerated antibiotic with a novel mechanism of action that is not affected by resistance to existing antibiotics, and that has a convenient, once-daily, oral dose.

Our Solution: Epetraborole

Epetraborole is a boron-containing, orally-available, 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.

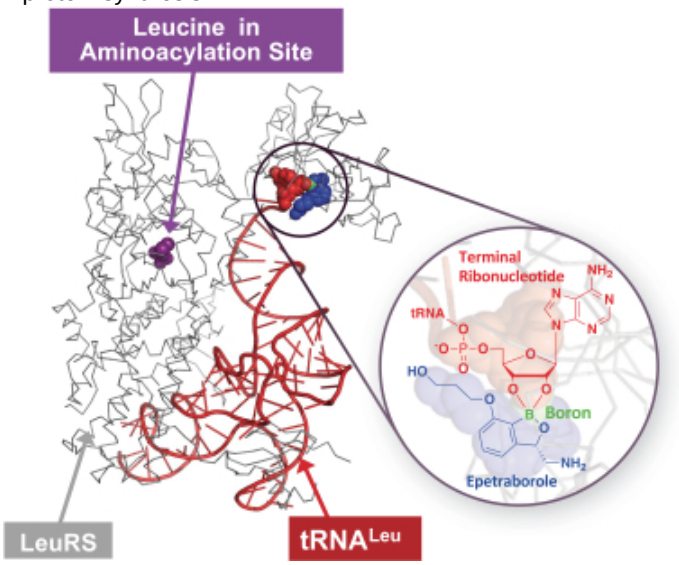


Figure A. Epetraborole inhibits the protein synthesis enzyme leucyl-tRNA synthetase (LeuRS) by binding to the terminal adenosine ribose of $tRNA^{Leu}$ in the editing site.

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

- Large market opportunity given the high unmet need in NTM lung disease and the potential 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;
- Substantial data package from the previously completed nonclinical and clinical studies conducted by Anacor and GlaxoSmithKline plc, or GSK, our recently completed chronic toxicology studies in two species, and our nearly concluded Phase 1b dose-ranging study;
- Convenient once-daily, oral dosing with the aim to serve as an important component of therapy for MAC lung disease; and
- Compatibility with guideline-based combination treatments.

Epetraborole has been administered intravenously or orally as a monotherapy 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 Anacor's previous partner GSK with a focus on gram-negative infections that were unrelated to NTM lung disease. Clinical resistance was observed in four of twenty patients in one of the two Phase 2 clinical trials. As a result, the two Phase 2 trials and two other Phase 1 trials were

terminated prior to completion. Clinical resistance occurs when bacteria, under drug pressure or through natural resistance, become less susceptible to an antibiotic. Clinical resistance is possible for all antibiotics and the rates and nature of emergence of resistance vary by bacterial species. Combination therapy has been shown to significantly reduce the risk of the emergence of clinical resistance. NTM is treated with combination therapy per treatment guidelines, which is distinct from earlier clinical trials of epetraborole in other infection types where monotherapy epetraborole was evaluated.

Although epetraborole was not tested by Anacor or GSK in patients with NTM lung disease, previous results from one of these trials, a Phase 1 trial conducted by GSK that measured the penetration of epetraborole into the lung, showed the exposure of epetraborole in alveolar (lung) macrophages, the cells that are infected with mycobacteria in NTM lung disease, was approximately five-fold higher than in plasma. In addition, epetraborole has demonstrated in vitro antibacterial activity against a panel of 51 isolates of MAC (*M. avium, M. intracellulare, and M. chimaera*) including against strains that are resistant to antibiotics currently used to treat NTM lung disease. We have completed six cohorts of a double-blind, placebo-controlled Phase 1b dose-ranging study of epetraborole in healthy volunteers to assess the pharmacokinetics of the molecule at oral doses lower than those previously investigated in prior clinical trials conducted by Anacor and GSK, and in the range of the expected clinical dose to obtain safety and tolerability data for 28-days of dosing. This dose-ranging study is being conducted in Adelaide, Australia in up to 51 healthy volunteers (with up to 39 volunteers receiving epetraborole). A total of 43 subjects were enrolled in the double-blind, placebo-controlled portion of the study (cohorts 1 through 6, including 31 epetraborole and 12 placebo subjects). We received interim unblinded data from these six cohorts in the fourth quarter of 2021 and data analysis is ongoing. Enrollment into the final food-effect cohort has started (8 subjects administered open-label epetraborole), and is pending completion.

We have designed a Phase 2/3 pivotal clinical trial that, based on three interactions to date with the FDA to discuss the design, including discussions regarding our nonclinical microbiology, toxicology, and pharmacology data package for epetraborole and interim data from our Phase 1b dose-ranging study, we believe has the potential to be sufficient for regulatory approval in the United States. We plan to enroll patients with treatment-refractory MAC lung disease in this double-blind, placebo-controlled superiority trial, with planned enrollment of approximately 260 patients across approximately 80 clinical sites in up to 6 countries in North America and Europe. We expect that the primary objective in the Phase 3 part of the trial will be to determine if epetraborole plus an optimized background regimen (OBR), consisting of two or more standard-of-care drugs, is superior to placebo plus an OBR. We are working with the FDA to finalize the primary endpoint for our planned clinical trial, for which the FDA recommends a clinical response measure. We expect that the secondary endpoints will include other microbiological, clinical, and safety measures. We recently received clearance of our IND application by the FDA, and we plan to initiate patient enrollment in our Phase 2/3 clinical trial in the first half of 2022 with topline results for the Phase 2 part of the trial anticipated in the middle of 2023 and the Phase 3 part of the trial anticipated in the middle of 2024.

We intend to conduct trials and pursue marketing authorizations with epetraborole in additional geographies outside of the United States and Europe, with an initial focus in Japan. We estimate that there are approximately 220,000 patients with NTM lung disease and approximately 21,000 patients with treatment-refractory MAC lung disease in Japan. We have initiated discussions with the Pharmaceutical and Medical Devices Agency, or PMDA, to gain alignment on the development plan necessary for regulatory approval of epetraborole in MAC lung disease. Our initial planned indication in all geographies is the treatment of patients with treatment-refractory MAC lung disease. We also intend to expand the indication targeted by epetraborole by pursuing development in other mycobacterial

diseases, including treatment-naïve MAC lung disease, which we believe is supported by data from our Phase 1b study and our existing nonclinical data package, and *Mycobacterium abscessus, or M. abscessus*, lung infections, which is also supported by the interim data from the Phase 1b study, but for which additional nonclinical work may be needed. Additionally, we have a strategic partnership with Brii Biosciences Limited, or Brii Biosciences, under which we have licensed out our rights to develop, manufacture, and commercialize epetraborole in China, Hong Kong, Taiwan, and Macau.

Our Strategy

Our mission is to develop novel therapeutics to treat rare, chronic, and serious infectious diseases in areas of high unmet medical need. Key components of our strategy to achieve this goal include:

- Advance epetraborole through clinical development in MAC lung disease with an initial focus on patients with treatment-refractory MAC lung disease;
- Develop epetraborole in additional territories and indications;
- Build and scale organizational capabilities to support commercialization of epetraborole in MAC lung disease;
- Continue to invest in expanding our pipeline of product candidates; and
- Apply our expertise in antimicrobial drug design and development to other global health problems.

Our Team

Our team is led by Eric Easom, M.B.A., M.Eng., our co-founder, president, and chief executive officer. Mr. Easom has over 31 years of leadership experience in the biotechnology and pharmaceutical industry, including the last 15 years in infectious disease. He previously led Anacor's research and development efforts in global health. Paul Eckburg, M.D., our chief medical officer, previously served as chief medical officer at a number of other biotechnology companies and was involved in the development of multiple approved antibiotics. Sanjay Chanda, Ph.D., our chief development officer, previously served as chief development officer at Tioma Therapeutics, Inc. and was senior vice president of drug development at Anacor. Lucy Day, our chief financial officer, previously served as chief financial officer at Anacor. Kevin Krause, M.B.A., our chief strategy officer, previously served in various roles at Achaogen, Inc., Cerexa, Inc., and Theravance, Inc. and has deep expertise in antibiotic research, development, and commercialization. Our team also includes George Talbot, M.D., FACP, FIDSA, our co-founder and clinical advisor, Joseph Zakrzewski, our co-founder and chairman of the board of directors, and two inventors of epetraborole, Vincent Hernandez, our vice president of chemistry, and Michael R.K. (Dickon) Alley, Ph.D., our head of biology and co-founder.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include, but are not limited to, the following:

- 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, which is in clinical development, but for which we have not yet initiated a planned Phase 2/3 pivotal 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 FDA, the European Medicines Agency, or EMA, the PMDA, the Therapeutic Goods Administration in Australia, or 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 EMA, 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.

Corporate Information

We were incorporated in February 2017 as a Delaware corporation and launched operations in November 2019. Our principal executive offices are located at 1800 El Camino Real, Suite D, Menlo Park, California 94027 and our telephone number is (650) 331-9090. Our website address is www.an2therapeutics.com. Information contained in, or accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is only an inactive textual reference.

Trademarks and Service Marks

We use the AN2 Therapeutics logo and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork, and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. We may take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions for up to five years or until we are no longer an "emerging growth company," whichever is earlier. We will cease to be an emerging growth company prior to the end of such five-year period if certain earlier events occur, including if (i) we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or Exchange Act, (ii) our annual gross revenues exceed $1.07 billion, or (iii) we issue more than $1.0 billion of non-convertible debt in any three-year period. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

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 provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies 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."

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may continue to be a smaller reporting company after this offering if either (i) the market value of our shares held by non-affiliates is less than $250 million as measured on the last business day of our second fiscal quarter or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million as measured on the last business day of our second fiscal quarter. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation. Further, if we are a smaller reporting company with less than $100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

The Offering	
Common stock offered by us	shares
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to an additional shares of our common stock at the initial public offering price, less underwriting discounts and commissions.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately $ million (or approximately $ million if the underwriters' option to purchase additional shares of our common stock from us is exercised in full), based on the assumed initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash, to: ▪ fund the clinical development of epetraborole for treatment-refractory NTM lung disease caused by MAC through the receipt of topline data from our planned Phase 2/3 pivotal clinical trial and to fund manufacturing and other pre-commercialization activities; ▪ fund the expansion of epetraborole in treatment-refractory MAC lung disease in other key markets, with an initial focus on Japan, as well as in other NTM indications such as treatment-naïve MAC lung disease and *M. abscessus* lung infections; and ▪ fund the further development of our AN2 drug discovery platform and for general corporate purposes, including working capital and operating expenses. See the section titled "Use of Proceeds" for additional information.

Risk factors	See the section titled “Risk Factors” and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Proposed Nasdaq Global Market trading symbol	“ANTX”

The number of shares of our common stock to be issued and outstanding, pro forma and pro forma as adjusted is based on 5,999,743 shares of common stock outstanding as of December 31, 2020, after giving effect to the issuance of 2,266,661 shares of Series B redeemable convertible preferred stock in March 2021, and the automatic conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock into an equivalent number of shares of our common stock upon the closing of this offering, and excludes:

- 127,343 shares of our common stock issuable upon the exercise of outstanding stock options as of December 31, 2020, with a weighted-average exercise price of $0.99 per share;
- 557,746 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to December 31, 2020 through December 31, 2021, with a weighted-average exercise price of $16.74 per share;
- shares of our common stock reserved for future issuance under our 2022 Equity Incentive Plan, or 2022 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2022 Plan; and
- shares of our common stock reserved for issuance under our 2022 Employee Stock Purchase Plan, or ESPP, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

Unless otherwise indicated, this prospectus assumes or gives effect to:

- the automatic conversion of all 2,582,403 shares of our outstanding redeemable convertible preferred stock as of December 31, 2020 and all 2,266,661 shares of our Series B redeemable convertible preferred stock issued in March 2021 into an equivalent number of shares of our common stock upon the closing of this offering;
- no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase additional shares of common stock from us in this offering;
- an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus; and
- the filing and effectiveness of our amended and restated certificate of incorporation to be in effect immediately after the closing of this offering and the adoption of our amended and restated bylaws upon the closing of this offering.

Summary Financial Data

The following tables set forth our summary financial data for the periods and as of the dates indicated. The following summary statements of operations for the years ended December 31, 2019 and 2020 have been derived from our audited financial statements included elsewhere in this prospectus. The following summary balance sheet data as of December 31, 2020 have been derived from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. You should read the following summary financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus. The summary financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by our financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2019	2020
	(in thousands, except share and per share data)	
Statements of Operations		
Operating expenses:		
Research and development	$ 187	$ 5,366
Research and development—related party	4,702	653
General and administrative	289	1,265
Total operating expenses	5,178	7,284
Loss from operations	(5,178)	(7,284)
Interest income	–	3
Other expense	(457)	(6,322)
Net loss	(5,635)	(13,603)
Accretion to redemption value and cumulative dividends on preferred stock	(99)	(981)
Net loss attributed to common stockholders	$ (5,734)	$ (14,584)
Net loss per share attributable to common shareholders, basic and diluted(1)	$ (5.29)	$ (13.36)
Weighted-average number of shares used in computing net loss per share, basic and diluted(1)	1,085,000	1,091,678
Pro forma net loss per share, basic and diluted(2)		$ (4.65)
Pro forma weighted-average number of shares used in computing pro forma net loss per share, basic and diluted(2)		3,135,969

(1) See Note 12 to our financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per common share and the number of shares used in computing these amounts.

(2) The pro forma basic and diluted net loss per share for the year ended December 31, 2020 has been prepared to give effect to an adjustment to the denominator in the pro forma basic and diluted net loss per share calculation for the automatic conversion of all 2,044,291 weighted-average outstanding shares of our redeemable convertible preferred stock as of December 31, 2020 into an equivalent number of shares of common stock.

	As of December 31, 2020		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2][3]
		(in thousands)	
Balance Sheet Data			
Cash	$ 4,070	$ 83,803	$
Working capital[4]	2,775	82,509	
Total assets	4,234	83,967	
Total liabilities	1,483	1,483	
Redeemable convertible preferred stock	23,070	–	
Accumulated deficit	(20,319)	(20,319)	
Total stockholders' (deficit) equity	(20,319)	82,484	

(1) The pro forma column in the balance sheet data gives effect to (i) the automatic conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock into an equivalent number shares of common stock (after giving effect to the issuance of 2,266,661 shares of Series B redeemable convertible preferred stock in March 2021), which will occur upon the closing of this offering, and the related reclassification of the carrying value of our redeemable convertible preferred stock to permanent equity upon the closing of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation to be in effect immediately after the closing of this offering.

(2) The pro forma as adjusted column in the balance sheet data gives effect to (i) the items described in footnote (1) above and (ii) the issuance and sale of shares of our common stock in this offering at the assumed initial public offering price of $ per share after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) The pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, each of our cash, working capital, total assets and total stockholders' deficit by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease, as applicable, each of our cash, working capital, total assets, and total stockholders' deficit by $ million and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(4) Working capital is defined as current assets less current liabilities. See our financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before you invest in our common stock, you should carefully consider the risks described below together with all of the other information contained in this prospectus, including our audited financial statements and unaudited condensed financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus. 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 $5.6 million and $13.6 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, we had an accumulated deficit of $20.3 million. We have funded our operations to date primarily with proceeds from 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 are still in the early stages of 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 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, identifying and 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 the net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 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 and 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, including purchasers of shares of our common stock in this offering, 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. We as a company have limited experience with non-dilutive funding, and we may not be able to obtain non-dilutive funding to support our needs. For example, we cannot be certain that there will be grants or funding sources available to support our development efforts, that our grant applications and funding proposals will be successful, or that we will be able to continue satisfying the award criteria of any grants or funding proposals awarded to us. If we fail to receive 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 yet initiated a planned Phase 2/3 pivotal 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 candidates 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 EMA, the PMDA, the TGA, and other comparable foreign regulatory authorities. To date, we have only conducted one clinical trial, in Australia. 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 could be caused by a variety of factors, including but not limited to, toxicity, safety, tolerability, efficacy, 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:

- approval of our future INDs;
- successful completion of preclinical and nonclinical studies and requisite clinical trials;
- performing preclinical studies and clinical trials in compliance with the FDA, EMA, PMDA, 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;
- avoid and defend against third-party infringement, misappropriation or other violation of intellectual property claims; and
- maintaining a continued acceptable safety and tolerability profile of our drugs following approval.

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, or GSK, 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 regimen used in our planned Phase 2/3 pivotal clinical trial will be safe, tolerable, or effective. We cannot guarantee that the dose selection approach—including input from preclinical infection models, preclinical mitigation of resistance development through use of combination antibiotic regimens, pharmacokinetic and pharmacodynamic modeling, plus pharmacokinetic and safety data from our Phase 1b dose-ranging study in healthy volunteers—will be validated in our planned Phase 2/3 pivotal clinical trial in patients with treatment-refractory MAC lung disease. The dosage regimen to be used in the planned single Phase 2/3 pivotal 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, may not be predictive of safety or efficacy results in our planned Phase 2/3 pivotal 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 planned Phase 2/3 pivotal 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 proposed clinical trial plan for epetraborole with the FDA.

We plan to conduct a single Phase 2/3 pivotal 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 Insmed 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 plan to conduct a single Phase 2/3 pivotal 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, including a separate Phase 2 clinical trial prior to the initiation of a Phase 3 clinical trial, rather than the planned registrational Phase 2/3 pivotal clinical trial.

The FDA can recommend study design element changes at any time, including, for example, 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 likely be required to demonstrate efficacy based on clinical 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 Phase 2/3 pivotal clinical trial may not be sufficient to determine whether the trial results will support approval of a product, 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. 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 EMA, the PMDA, 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 EMA, the PMDA, 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 EMA, the PMDA, 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 planned epetraborole Phase 2/3 pivotal 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;
- the number of patients required for clinical trials of epetraborole and any of our future product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate, or we may fail to recruit suitable patients to participate in a trial;
- 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 EMA, the PMDA, 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 EMA, the PMDA, 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 the 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 planned registrational Phase 2/3 pivotal 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 EMA, the PMDA, 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 were gastrointestinal in nature. Additional adverse events may emerge in any subsequent clinical trials and there may be unforeseen serious adverse events or side effects that differ from those seen in studies completed to date. Often, it is not possible to determine whether or not a product candidate being studied caused side effects. 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 EMA, the PMDA, 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 EMA, the PMDA, 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 planned Phase 2/3 pivotal 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 may affect the timing of our planned clinical trials. For example, 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. 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 actions taken to mitigate its 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 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 supply and drug product manufacture 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 the identifying, qualifying, and contracting with a U.S. 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 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 EMA, the PMDA, 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 regiment;
- the approval of other new products for the same indications;
- the timing of market introduction of the approved product as well as competitive products;
- the emergence of bacterial resistance to the product; and
- the rate at which resistance to other 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 EMA, the PMDA, 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, 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 EMA, the PMDA, 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 EMA, the PMDA, 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 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 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, we intend to build a commercial organization to target areas with the greatest incidence 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 epetraborole 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 global product liability insurance coverage with a per incident limit of $5.0 million and an AUD $10.0 million product liability insurance coverage for the Phase 1b dose-ranging study in Australia with a per incident limit of AUD $10.0 million, 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 epetraborole or any future product candidates internationally, which could affect our business.

We may seek regulatory approval for epetraborole 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.

We currently have limited personnel: as of October 31, 2021, we had 22 full-time employees. We are highly dependent on the management, research and development, clinical, financial, and business development expertise of Eric Easom, M.B.A, M.Eng., 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, Kevin Krause, M.B.A., our chief strategy officer, George H. Talbot, M.D., FACP, FIDSA, our co-founder and senior clinical advisor, 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 of them may currently terminate their employment with us at any time and will continue to be able to do so after the completion of this offering. 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 any of epetraborole 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, 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 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. 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. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic, which may delay enrollment in our 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.

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 this offering, we have 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, 2019 and 2020. Additionally, these material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

- We did not design and maintain effective controls over information technology (IT) general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain (i) program change management controls to ensure that 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 in the process of 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), initiating 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) initiating and designing 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, 2022. 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 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 The Nasdaq Global Market, the 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 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 to Brii 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 our 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 or 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 court 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 Class A 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 Class A 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 Europe and 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 EMA, 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 are seeking orphan drug designation for epetraborole and we may seek orphan drug designation 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 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. There can be no assurance that the FDA will grant orphan designation for any indication for which we apply. Similar laws exist in Europe and Japan.

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. If a competitor obtains approval of the same drug for the same indication or disease before us, we would be blocked from obtaining approval for epetraborole for seven or more years, unless epetraborole can be shown to be clinically superior. 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, if epetraborole is approved and receives orphan drug status, 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.

We have recently 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, and may continue to seek, Fast Track designation or Breakthrough Therapy designation from the FDA, for certain of our product candidates, 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 recently received Fast Track designation by the FDA to investigate epetraborole for treatment-refractory MAC lung disease. We may continue to seek Fast Track designation or Breakthrough Therapy 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 intend to 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 intend to 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.

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 the European Union, United Kingdom, Japan, 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 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 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, or to disclose unauthorized activities to us. 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 (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) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. As of January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners; 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 epetraborole 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. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. 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. In addition, recently 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. Further, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. 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 epetraborole 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 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.

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

If you purchase common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price per share of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share. Therefore, if you purchase common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $ per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the assumed initial public offering price per share. After this offering, we will also have outstanding options to purchase shares of our common stock with exercise prices lower than the initial public offering price. To the extent these outstanding options are exercised, there will be further dilution to investors in this offering. For further information regarding the dilution resulting from this offering, see the section titled “Dilution” in this prospectus.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to the restrictions and limitations described below. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market following this offering, the market price of our common stock could decline significantly.

Upon the closing of this offering, we will have outstanding shares of common stock, after giving effect to the conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock into an equivalent number of shares of common stock, assuming no exercise of the underwriters’ overallotment option and no exercise of outstanding options. Of these shares, the shares sold in this offering will be freely tradable and the remaining shares of common stock will be available for sale in the public market beginning after the end of the 180th day after the date of this prospectus following the expiration of lock-up agreements between our stockholders and certain of the underwriters for this offering, subject, in the case of our affiliates, to the conditions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. , on behalf of the underwriters, may release these stockholders from their lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market subject to the conditions of Rule 144 under the Securities Act.

In addition, promptly following the closing of this offering, we intend to file one or more registration statements on Form S-8 registering the issuance of approximately million shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Additionally, after this offering, the holders of an aggregate of shares of our common stock, or their transferees, will have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we

may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market without limitation. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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.

Upon completion of this offering, our executive officers, directors, and current beneficial owners of 5% or more of our common stock and their respective affiliates will, in the aggregate, beneficially own % of our outstanding common stock, based on the number of shares of our common stock outstanding as of , 2021 and after giving effect to the conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock (including the issuance of 2,266,661 shares of Series B redeemable convertible preferred stock in March 2021), into an equivalent number of shares of common stock, assuming no exercise of the underwriters' overallotment option and no exercise of outstanding options. Assuming an initial public offering price of $ per share, if our existing principal stockholders and their respective affiliates purchase all of the shares of common stock they have indicated an interest in purchasing in this offering, the number of shares of common stock beneficially owned by our existing executive officers, directors, and principal stockholders (and their affiliates) will, in the aggregate, increase to % 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;
- 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 are being sold in this offering 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.

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 that will become effective upon the completion of this offering 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 of directors 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 of directors. 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 of directors;
- 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 of directors;
- 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 of directors 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 of directors; 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 will provide 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 will provide 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 will also provide 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 proceeds from this offering and may invest or spend the proceeds 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, including the net proceeds from this offering, and could spend the proceeds 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 epetraborole and planned pipeline and expansion programs as well as commercial preparedness. Pending their use, we may invest our cash, including the net proceeds from this offering, in a manner that does not produce value or that loses value. See the section titled "Use of Proceeds" for additional information.

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, 2020, we had federal and state net operating loss, or NOLs, carryforwards of approximately $12.2 million and $12.4 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 as a result of this offering and/or subsequent shifts in our stock ownership (some of which may be outside our control). 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. For example, California recently imposed limits on the usability of California state NOLs and tax credits to offset California taxable income in tax years beginning after December 31, 2019 and before January 1, 2023. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

General Risk Factors

An active trading market for our common stock may not develop and you may not be able to resell your shares at or above the initial offering price, if at all.

This offering constitutes the initial public offering of our common stock, and no public market has previously existed for our common stock. We have applied to list our common stock on The Nasdaq Global Market. Any delay in the commencement of trading of our common stock on The Nasdaq Global Market would impair the liquidity of the market for the shares and make it more difficult for holders to sell their shares of our common stock. If our common stock is listed and quoted on The Nasdaq Global Market, there can be no assurance that an active trading market for the shares will develop or be sustained after this offering is completed. The initial offering price will be determined by negotiations among the lead underwriters and us. Among the factors to be considered in determining the initial public offering price are our future prospects and the prospects of our industry in general, our financials and certain other financial and operating information in recent periods, and the market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. However, there can be no assurance that, following the completion of this offering, the shares of our common stock will trade at a price equal to or greater than the public offering price.

The trading price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering 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 prospectus, these factors include:

- the commencement, enrollment, or results of our planned and future clinical trials;
- 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 epetraborole or any future product candidates;
- changes to our relationships with collaborators, manufacturers, or suppliers;
- the results of our testing and clinical trials;
- unanticipated safety, tolerability, or efficacy concerns;
- 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 Market;
- sales of our common stock by us, our executive officers and directors or our stockholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States or the United Kingdom (including those relating to macroeconomic events, such as the COVID-19 pandemic);
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry; 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 do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock after the completion of this offering, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, 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 will incur significantly increased costs as a result of operating as a company whose common stock is publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a public company in the United States, we will incur significant legal, accounting, and other expenses that we did not incur previously. 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, 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. We cannot predict or estimate the amount of additional costs we may 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 will be 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, potentially 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 prospectus. In particular, in this prospectus, we have provided only two years of audited 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, 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 prospectus include, but are not limited to, statements about:

- our use of the net proceeds from this offering;
- 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 ability of our planned Phase 2/3 clinical trial in MAC lung disease to be sufficient for regulatory approval in the United States;
- our ability to retain the continued service of our key professionals and to identify, hire, and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the commercialization of our product candidates, if approved;
- the ability of epetraborale, if approved, to successfully compete with other therapies, including therapies currently in development;
- the pricing, coverage, and reimbursement of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business, and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- our ability to identify additional product candidates and advance them into clinical development;
- our estimates regarding expenses, capital requirements, and needs for additional financing;
- our financial performance; and
- developments relating to our competitors and our industry.

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 prospectus and are subject to a number of risks, uncertainties, and assumptions described in the section titled “Risk Factors” and elsewhere in this

prospectus. 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 prospectus, 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 prospectus, 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.

MARKET, INDUSTRY, AND OTHER DATA

We obtained the industry, market, and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry, and general publications and surveys, governmental agencies, and publicly available information in addition to research, surveys, and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market, and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately $ million (or approximately $ million if the underwriters' option to purchase additional shares of our common stock is exercised in full) based on the assumed initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $ million, assuming the initial public offering price of $ per share remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and facilitate our future access to the public capital markets.

We currently intend to use the net proceeds we receive from this offering, together with our existing cash, as follows:

- approximately $ to fund the clinical development of epetraborole for treatment-refractory NTM lung disease caused by MAC through the receipt of topline data from our planned Phase 2/3 pivotal clinical trial and to fund manufacturing and other pre-commercialization activities;
- approximately $ to fund the expansion of epetraborole in treatment-refractory MAC lung disease in other key markets, with an initial focus on Japan, as well as in other NTM indications such as treatment-naïve MAC lung disease and *M. abscessus* lung infections; and
- the remainder to fund the further development of our AN2 drug discovery platform and for general corporate purposes, including working capital and operating expenses.

We may also use a portion of the net proceeds and our existing cash to in-license, acquire, or invest in complementary businesses, technology platforms, products, or assets. However, we have no current commitments or obligations to do so.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash, will be sufficient to fund our operations for at least the next 24 months. Our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the closing of this offering or the actual amounts that we will spend on the uses set forth above. The net proceeds from this offering, together with our existing cash, will not be sufficient for us to fund epetraborole through regulatory approval, and we anticipate needing to raise additional capital to commercialize epetraborole and to develop any future product candidates.

The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our planned clinical trials, the results of our planned clinical trials

and other factors described in the section titled “Risk Factors” in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes. We will have broad discretion over how to use the net proceeds to us from this offering. We intend to invest the net proceeds to us from this offering that are not used as described above in short-term, investment-grade, interest-bearing instruments.

DIVIDEND POLICY

We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects, and other factors our board of directors may deem relevant. In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

CAPITALIZATION

The following table sets forth our cash and capitalization as of December 31, 2020:

- on an actual basis;
- on a pro forma basis, giving effect to the (i) issuance of 2,266,661 shares of our Series B redeemable preferred stock in March 2021 for net proceeds of approximately $79.7 million, (ii) automatic conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock into an equivalent number of shares of our common stock, which will occur upon the closing of this offering, and the related reclassification of the carrying value of our redeemable convertible preferred stock to permanent equity upon the closing of this offering, and (iii) filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering; and
- on a pro forma as adjusted basis, giving effect to the (i) pro forma adjustments set forth above and (ii) our receipt of net proceeds from the sale of shares of common stock in this offering at the assumed initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Description of Capital Stock,” and our financial statements and the related notes included elsewhere in this prospectus.

	As of December 31, 2020		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share amounts)		
Cash	$ 4,070	$ 83,803	$
Series A redeemable convertible preferred stock, $0.00001 par value per share; 2,582,403 shares authorized, 2,582,403 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma, and pro forma as adjusted	$ 23,070	$ –	$
Series B redeemable convertible preferred stock, $0.00001 par value per share; no shares authorized, issued and outstanding, actual, pro forma, and pro forma as adjusted	–	–	
Stockholders’ (deficit) equity:			
Preferred stock, $0.00001 par value per share; no shares authorized, issued or outstanding, actual; shares authorized, pro forma and pro forma as adjusted; no shares issued or outstanding, pro forma, and pro forma as adjusted	–	–	
Common stock, $0.00001 par value per share; 7,295,839 shares authorized, 1,150,679 shares issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted; 5,999,743 shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted	–	–	
Additional paid-in capital	–	102,803	
Accumulated deficit	(20,319)	(20,319)	
Total stockholders’ (deficit) equity	(20,319)	82,484	
Total capitalization	$ 2,751	$ 82,484	

The pro forma as adjusted information above is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, each of our pro forma as adjusted cash, additional paid-in capital, total stockholders' deficit and total capitalization by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares common stock offered by us would increase or decrease, as applicable, each of our pro forma as adjusted cash, additional paid-in capital, total stockholders' deficit, and total capitalization by approximately $ million, assuming the assumed initial public offering price of $ per share remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock to be issued and outstanding, pro forma, and pro forma as adjusted in the table above is based on 5,999,743 shares of common stock outstanding as of December 31, 2020, after giving effect to the issuance of 2,266,661 shares of Series B redeemable convertible preferred stock in March 2021, and the automatic conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock into an equivalent number of shares of our common stock upon the closing of this offering, and excludes:

- 127,343 shares of our common stock issuable upon the exercise of outstanding stock options as of December 31, 2020, with a weighted-average exercise price of $0.99 per share;
- 557,746 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to December 31, 2020 through December 31, 2021, with a weighted-average exercise price of $16.74 per share;
- shares of our common stock reserved for future issuance under our 2022 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2022 Plan; and
- shares of our common stock reserved for issuance under our ESPP, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per share of common stock and the pro forma as adjusted net tangible book value per share immediately after this offering.

As of December 31, 2020, we had a historical net tangible book deficit of $20.3 million, or $17.66 per share of common stock based on the 1,150,679 shares of common stock outstanding as of such date. Our historical net tangible book value (deficit) per share represents total tangible assets less total liabilities and redeemable convertible preferred stock, which is not included within permanent equity, divided by the number of shares of common stock outstanding as of December 31, 2020.

Our pro forma net tangible book value as of December 31, 2020 was $2.8 million, or $0.46 per share. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by 5,999,743 shares of common stock outstanding as of such date, after giving effect to (i) the issuance of 2,266,661 shares of our Series B redeemable convertible preferred stock in March 2021 for net proceeds of approximately $79.7 million, (ii) the automatic conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock into an equivalent number of shares of our common stock and the related reclassification of the carrying value of our redeemable convertible preferred stock to permanent equity upon the closing of this offering, and (iii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering.

After giving effect to the sale by us of shares of common stock in this offering at the assumed initial public offering price of $ per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2020 would have been $ million, or $ per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of $ per share to investors purchasing common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash paid by an investor for a share of common stock in this offering. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Historical net tangible book deficit per share as of December 31, 2020	$(17.66)	
Pro forma increase in historical net tangible book value per share attributable to the pro forma transaction described in the preceding paragraphs	$ 18.12	
Pro forma net tangible book value per share as of December 31, 2020	$ 0.46	
Increase in pro forma as adjusted net tangible book value per share attributable to investors purchasing shares in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution in pro forma as adjusted net tangible book value per share to investors purchasing shares in this offering		$

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering. Each $1.00 increase or decrease in the

assumed initial public offering price of $ per share would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share after this offering by $ per share and increase or decrease, as applicable, the dilution to investors purchasing shares in this offering by $ per share, in each case assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease our pro forma as adjusted net tangible book value by approximately $ per share and decrease or increase, as applicable, the dilution to investors purchasing shares in this offering by approximately $ per share, in each case assuming the assumed initial public offering price of $ per share remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of common stock in full, the pro forma net tangible book value per share, as adjusted to give effect to this offering, would be $ per share, and the dilution in pro forma net tangible book value per share to investors in this offering would be $ per share.

The foregoing discussion and tables above (other than the historical net tangible book value calculation) are based on 5,999,743 shares of common stock outstanding as of December 31, 2020, after giving effect to the issuance of 2,266,661 shares of Series B redeemable convertible preferred stock in March 2021, and the automatic conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock into an equivalent number of shares of our common stock upon the closing of this offering, and excludes:

- 127,343 shares of our common stock issuable upon the exercise of outstanding stock options as of December 31, 2020, with a weighted-average exercise price of $0.99 per share;
- 557,746 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to December 31, 2020 through December 31, 2021, with a weighted-average exercise price of $16.74 per share;
- shares of our common stock reserved for future issuance under our 2022 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2022 Plan; and
- shares of our common stock reserved for issuance under our ESPP, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus 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 in the section titled "Risk Factors." 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 chronic NTM 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. We have completed six cohorts of a Phase 1b dose-ranging study of epetraborole administered orally for 28 days in healthy volunteers in Australia, with a last food-effect cohort remaining to be completed, and completed two nonclinical chronic toxicology studies (6-month rat and 9-month non-human primates), which will inform dose selection for our Phase 2/3 clinical trial and may inform dose selection for any additional clinical trials in NTM patients. A Phase 2/3 pivotal clinical trial design in treatment-refractory MAC lung disease, which is the most common type of NTM lung disease and which we believe has the potential to be sufficient for regulatory approval in the United States, is under review with the FDA. We recently received clearance of our IND application by the FDA, and plan to initiate patient enrollment in our Phase 2/3 clinical trial in the first half of 2022 with topline results for the Phase 2 part of the trial anticipated in the middle of 2023 and the Phase 3 part of the trial anticipated in the middle of 2024. We also recently received Fast Track designation by the FDA to investigate epetraborole for treatment-refractory MAC lung disease. Epetraborole has also recently been designated as a QIDP for treatment-refractory MAC lung disease by the FDA. 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, upon the completion of this offering, 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 $5.6 million and $13.6 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, we had an accumulated deficit of $20.3 million. We have funded our operations from the sale and issuance of redeemable convertible preferred stock. In November 2019 and October 2020, we raised an aggregate of $12.0 million from the sale of Series A redeemable convertible preferred stock. As of December 2020, we had a cash balance of $4.1 million. In March 2021, we raised net cash proceeds of $79.7 million from the sale of Series B redeemable

convertible preferred stock. We believe that our available cash will be sufficient to fund our planned operations for at least 12 months following the date of this offering.

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, or CROs, and contract manufacturing organizations, or 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 epetraborole 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.

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.

In November 2019, we entered into an exclusive worldwide license agreement with Anacor Pharmaceuticals, Inc., or Anacor, for certain compounds and other intellectual property controlled by Anacor for the treatment, diagnosis, or prevention of all human diseases. 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 and issued Anacor 466,376 shares of Series A redeemable convertible preferred stock in November 2019, and an additional 112,688 shares in October 2020 in conjunction with the first and second closings of our Series A financing, respectively. For financial reporting purposes, the fair market value of the shares issued to Anacor was $5.79 per share, as compared to the Series A issuance price of $5.99 per share for the 2,003,339 shares of Series A redeemable convertible preferred stock that we issued and sold in November 2019 through December 2020 for an aggregate purchase price of approximately $15.4 million. See “Business—License Agreement with Anacor Pharmaceuticals, Inc.” for additional information.

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. Our research and development costs include internal costs, such as payroll and other personnel expenses, and external costs, such as license payments and fees paid to third parties to conduct

research and development activities on our behalf. The following table shows our research and development expenses by type of activity:

	Year Ended December 31,	
	2019	2020
	(in thousands)	
License agreement—related party	$4,702	$ 653
Clinical, nonclinical and preclinical expenses	131	2,688
Chemistry, Manufacturing and Controls (CMC) expenses	47	2,359
Regulatory and other expenses	9	319
Total research and development expenses	$4,889	$6,019

We expect our research and development expenses to increase substantially following this offering, and 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, in the future, we will be 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 prospectus 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, and general legal 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 The Nasdaq Global Market and the SEC, directors and officers liability insurance premiums and investor relations activities.

Interest Income

Interest income consists of interest income earned on our cash deposits.

Other Expense

Other expense consists of changes to the estimated fair value of the redeemable convertible preferred stock tranche liability.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2020

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

	Year Ended December 31,			
	2019	2020	Change	% Change
	(in thousands, except percentages)			
Operating Expenses:				
Research and development	$ 187	$ 5,366	$ 5,179	2770%
Research and development—related party	4,702	653	(4,049)	(86)
General and administrative	289	1,265	976	338
Total operating expenses	5,178	7,284	2,106	41
Loss from operations	(5,178)	(7,284)	(2,106)	(41)
Interest income	–	3	3	–
Other expense	(457)	(6,322)	(5,865)	(1283)
Net loss	$(5,635)	$(13,603)	$(7,968)	(141)

Research and Development Expenses

Research and development expenses were $0.2 million for the year ended December 31, 2019 compared to $5.4 million for the year ended December 31, 2020. The increase of $5.2 million was primarily due to increases in personnel-related expenses and expenses related to outside services, consultants and manufacturing. Personnel-related costs increased by $1.5 million, as a direct result of our increased research and development headcount. Outside services and consultants increased by $3.7 million for preclinical testing and manufacturing.

Research and Development Expenses—Related Party

Research and development expenses—related party were $4.7 million for the year ended December 31, 2019 compared to $0.7 million for the year ended December 31, 2020. The decrease of $4.0 million was a result of our $4.7 million up-front payment to Anacor and issuance of redeemable convertible preferred stock to Anacor in 2019 and the $0.7 million issuance of redeemable convertible preferred stock to Anacor in 2020. See “Business—License Agreement with Anacor Pharmaceuticals, Inc.” for additional information.

General and Administrative Expenses

General and administrative expenses were $0.3 million for the year ended December 31, 2019 compared to $1.3 million for the year ended December 31, 2020. The increase of $1.0 million was primarily attributable to a $0.8 million increase in personnel-related costs as we expanded our headcount, and a $0.2 million increase in outside services for patent and professional services to support our ongoing operations.

Interest Income

Interest income was immaterial for the years ended December 31, 2019 and 2020.

Other Expense

Other expense was $0.5 million during the year ended December 31, 2019 compared to other expense of $6.3 million for the year ended December 31, 2020. The other expense increase was attributable to an increase in the fair value of the redeemable convertible preferred stock tranche liability of $6.3 million.

Liquidity and Capital Resources

Sources of Liquidity

From our inception through October 31, 2021, we have funded our operations through private placements of our redeemable convertible preferred stock and have raised net cash proceeds of $91.6 million from the issuance of our redeemable convertible preferred stock. Key financing and corporate milestones include:

- 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.

Additionally, we do not expect positive cash flows from operations in the foreseeable future.

Future Funding Requirements

We have incurred net losses since our inception. For the years ended December 31, 2019 and 2020, we had net losses of $5.6 million and $13.6 million, respectively, and we expect to incur substantial additional losses in future periods. As of December 31, 2020, we had an accumulated deficit of $20.3 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 this offering.

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 of 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, current and future 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, following the completion of this offering, we expect to incur additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

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 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 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 prospectus 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,	
	2019	2020
	(in thousands)	
Cash used in operating activities	$(2,486)	$(5,364)
Cash provided by financing activities	8,084	3,836
Net increase/(decrease) in cash	$ 5,598	$(1,528)

Cash Used in Operating Activities

Net cash used in operating activities was $2.5 million for the year ended December 31, 2019. Cash used in operating activities was primarily due to the use of funds in our operations to start up and commence operations and initiate development of our initial product candidate resulting in a net of loss of $5.6 million and an increase in prepaid expenses and other current assets of $0.1 million, partially offset by the non-cash expense on issuance of our Series A redeemable convertible preferred stock in connection with the Anacor license agreement of $2.7 million and the change in fair value of our redeemable convertible preferred stock tranche liability of $0.5 million.

Net cash used in operating activities was $5.4 million for the year ended December 31, 2020. Cash used in operating activities was primarily due to the use of funds in our operations to develop our initial product candidate resulting in a net loss of $13.6 million and an increase in prepaid expenses and other current assets of $0.1 million, partially offset by the non-cash expense on issuance of our Series A redeemable convertible preferred stock in connection with the Anacor license agreement of $0.7 million, the change in fair value of our redeemable convertible preferred stock tranche liability of $6.3 million and an increase in accounts payable and accrued liabilities of $1.3 million due to an increase in accrued research and development expenses and accrued compensation.

Cash Provided by Financing Activities

Net cash provided by financing activities was $8.1 million for the year ended December 31, 2019, which consisted of net proceeds from the first closing of our Series A redeemable convertible preferred stock.

Net cash provided by financing activities was $3.8 million for the year ended December 31, 2020, which consisted primarily of net proceeds from the second closing of our Series A redeemable convertible preferred stock.

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 466,376 shares of Series A Preferred Stock in November 2019, and an additional 112,688 shares in October 2020 in conjunction with the first and second closings of our Series A redeemable convertible preferred stock financing, respectively. For financial reporting purposes, the fair market value of the shares issued to Anacor was $5.79 per share, as compared to the issuance price of $5.99 per share for the 2,003,339 shares of Series A redeemable convertible preferred stock that we issued and sold in November 2019 through December 2020 for an aggregate purchase price of approximately $15.4 million. 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. See “Business—License Agreement with Anacor Pharmaceuticals, Inc.” for additional information.

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.

Accrued Research and Development

We have entered into various agreements with CMOs and CROs. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the receipt of deliverables or completion of agreed-upon events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. 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. Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses until the services are rendered. To date, our estimated accruals have not differed materially from the actual costs.

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 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 to our audited financial statements included elsewhere in this prospectus 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 year ended December 31, 2020. 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 do not have any 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.
- ***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.
- ***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.

For the year ended December 31, 2020, the total intrinsic value of stock option awards exercised was immaterial, determined at the date of option exercise, and the total cash received upon exercise of stock options was $0.06 million. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying stock option awards and the estimated fair value of the common stock on the date of exercise.

Common Stock Valuations

The estimated fair value of the common stock underlying our stock options was determined at each grant date by our board of directors, 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.

In the absence of a public trading market for our common stock, on each grant date, we develop 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, 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.
- **Probability-Weighted Expected Return Method.** The probability-weighted expected return method, or PWERM, 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.

As we had a recent arms-length financing of our Series A redeemable convertible preferred stock near our last valuation date prior to December 31, 2020, we determined that the subject company transaction method under the market approach was the most appropriate method for determining enterprise value. 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, 2020, 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. In determining the estimated fair value of our common stock, our board of directors 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 this offering, the fair value of our common stock will be based on the closing quoted market price of our common stock on the date of grant.

Income Taxes

We provide for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities arise due to differences between when assets or liabilities are recognized for tax purposes and when they are recognized for financial reporting purposes. Net operating losses and credit carryforwards are also deferred tax assets. Deferred tax assets and liabilities are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized.

We assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination that the position meets the more-likely-than-not threshold and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement.

As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and we will determine whether the factors underlying the more-likely-than-not threshold assertion have changed and the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available. Our policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged as we had no recorded uncertain tax positions.

Net operating loss carryforwards and tax credit carryforwards are subject to review and possible adjustment by the IRS and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percentage points as defined under Sections 382 and 383 in the Internal Revenue Code, which could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. While we do not believe we have experienced ownership changes in the past, it is possible we have done so, and we may experience ownership changes in the future as a result of this offering and/or subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, even if we attain profitability, we may be limited in our ability to utilize our NOLs and other tax attributes.

Redeemable Convertible Preferred Stock

We record 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 is 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 will become redeemable at the option of the holders of at least a majority of the then outstanding such shares. In addition, shares of preferred stock must be redeemed by the Company at a price of $5.99 and $35.29 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, 2019 and 2020, we have accreted $0.1 million and $1.0 million, respectively, to the redemption value of the redeemable convertible preferred stock representing cumulative dividends.

Redeemable Convertible Preferred Stock Tranche Liability

The redeemable convertible preferred stock issued in November 2019 contained an embedded feature that provides the investors the ability to participate in a second close of the Series A at the same price upon the attainment of a specific milestone. The obligation to issue additional shares of Series A redeemable convertible preferred stock at a future date was determined to be a freestanding instrument that should be accounted for as a liability. At initial recognition, the Company recorded the redeemable convertible preferred stock tranche liability on the balance sheets at its estimated value. The redeemable convertible preferred stock tranche liability is subject to remeasurement at each subsequent reporting date, with changes in fair value recognized as a component of other expense. Immediately prior to the settlement of the tranche financing occurring in October 2020, the Company remeasured the redeemable convertible preferred stock tranche liability, with the change in fair value recognized as a component of other expense. The redeemable convertible preferred stock tranche liability was then reclassified to the redeemable convertible preferred stock. The estimated fair value of the redeemable convertible preferred stock tranche liability was $0.3 million at issuance and $7.1 million at settlement.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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.

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 $1.07 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 initial public offering.

Recent Accounting Pronouncements

See the section titled "Summary of Significant Accounting Policies—Recent Accounting Pronouncements" in Note 2 to our financial statements included elsewhere in this prospectus for additional information.

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 of $4.1 million as of December 31, 2020, which consisted of cash deposits.

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 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.

Foreign Currency Risk

A 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.

BUSINESS

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 chronic NTM 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. We have a Phase 1b dose-ranging study of epetraborole administered orally for 28 days in healthy volunteers in Australia, with a last food-effect cohort remaining to be completed, and completed two nonclinical chronic toxicology studies (6-month rat and 9-month non-human primates), which will inform dose selection for our Phase 2/3 clinical trial and may inform dose selection for any additional clinical trials in NTM patients. A Phase 2/3 pivotal clinical trial design in treatment-refractory MAC lung disease, which is the most common type of NTM lung disease and which we believe has the potential to be sufficient for regulatory approval in the United States, is under review with the FDA. We recently received clearance of our IND application by the FDA, and plan to initiate patient enrollment in our Phase 2/3 clinical trial in the first half of 2022 with topline results for the Phase 2 part of the trial anticipated in the middle of 2023 and the Phase 3 part of the trial anticipated in the middle of 2024. We also recently received Fast Track designation by the FDA to investigate epetraborole for treatment-refractory MAC lung disease. Epetraborole has also recently been designated as a QIDP for treatment-refractory MAC lung disease by the FDA. 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.

Our core technology approach is based on the use of boron chemistry for our drug research and development initiatives. Boron chemistry has proven to be a highly productive technology leading to the discovery of many promising drugs, particularly focused in infectious diseases. Pioneering work at Anacor Pharmaceuticals, Inc., or Anacor, acquired by Pfizer Inc. in 2016, led to the generation of a class of boron compounds including two FDA-approved therapies, Kerydin and Eucrisa. Our founders consist of former leaders at Anacor, including an inventor of epetraborole and a leading infectious disease expert. We have in-licensed the exclusive worldwide development and commercialization rights for epetraborole from Anacor. We believe our management team's expertise in boron chemistry, infectious diseases, and regulatory approvals will help drive the rapid development and, if approved, the commercialization of novel therapies for infectious diseases.

We are developing oral epetraborole for the treatment of 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. 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.

There are an estimated 200,000 patients with NTM lung disease in the United States; however, 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 incidence of NTM lung disease is increasing in the U.S. 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, or 15,000 patients, have treatment-refractory MAC lung disease. There are approximately 20,000 total NTM patients in Europe, of which 5,600 are estimated to have treatment-refractory MAC lung disease.

There is only one FDA-approved therapy for treatment-refractory MAC lung disease: Arikayce, an inhaled liposomal formulation of amikacin. In a clinical trial, the addition of Arikayce to standard of care combination antibiotic therapy resulted in the resolution of MAC infection in only 29% of patients, leaving more than 70% of treatment-refractory patients with limited or no treatment options. Furthermore, Arikayce has significant tolerability and safety issues, resulting in a boxed warning for risk of increased respiratory adverse reactions, and other warnings and precautions including ototoxicity, a known class effect with aminoglycosides, and other safety findings. Between 20.3% and 33.5% of patients treated with Arikayce in clinical trials discontinued treatment. Despite these shortcomings, Insmed reported net sales of Arikayce of over $160 million in the United States in 2020, only its second year on the market. We believe improved treatment of NTM lung disease will require an efficacious, safe, and well-tolerated antibiotic with a novel mechanism of action that is not affected by resistance to existing antibiotics, and that has a convenient, once-daily, oral dose.

Epetraborole is a boron-containing, orally-available, 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. Epetraborole has been administered intravenously or orally 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 Anacor's previous partner GlaxoSmithKline plc, or 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 Phase 2 clinical trials. Although epetraborole was not tested by Anacor or GSK in patients with NTM lung disease, previous results from one of these trials, a Phase 1 trial conducted by GSK that measured the penetration of epetraborole into the lung, showed the exposure of epetraborole in alveolar (lung) macrophages, the cells that are infected with mycobacteria in NTM lung disease, was approximately five-fold higher than in plasma. In addition, epetraborole has demonstrated in vitro antibacterial activity against a panel of 51 isolates of MAC (*M. avium*, *M. intracellulare*, and *M. chimaera)* including against strains that are resistant to antibiotics currently used to treat NTM lung disease.

We have completed six cohorts of a double-blind, placebo-controlled Phase 1b dose-ranging study of epetraborole in healthy volunteers to assess the pharmacokinetics of the molecule at oral doses lower than those previously investigated in prior clinical trials conducted by Anacor and GSK, and in the range of the expected clinical dose, to obtain safety and tolerability data for 28 days of dosing. The first five dosing cohorts have completed the 28-day dosing period and a sixth cohort was truncated after the enrollment of two patients. We received interim unblinded data from the Phase 1b dose-ranging study of these six cohorts in the fourth quarter of 2021 and data analysis is ongoing. Enrollment has begun in the final, open label, food-effect cohort and remains to be completed.

We have designed a Phase 2/3 pivotal clinical trial that, based on our three interactions to date with the FDA to discuss the design, including discussions regarding our nonclinical microbiology, toxicology, and pharmacology data package for epetraborole and interim data from our Phase 1b dose-ranging study, we believe has the potential to be sufficient for regulatory approval in the United States. We plan to enroll patients with treatment-refractory MAC lung disease in this double-blind, placebo-controlled superiority trial, with planned enrollment of approximately 260 patients across approximately 80 clinical sites in up to 6 countries in North America and Europe. We expect that the primary objective in the Phase 3 part of the trial will be to determine if epetraborole plus an optimized background regimen, or OBR, consisting of two or more standard-of-care drugs, is superior to placebo plus an OBR. We are working with the FDA to finalize the primary endpoint for our planned clinical trial, for which the FDA recommends a clinical response measure. We expect that the secondary endpoints will include other microbiological, clinical, and safety measures. We recently received clearance of IND application by the FDA, and we plan to initiate patient enrollment in our Phase 2/3 clinical trial in the first half of 2022 with topline results for the Phase 2 part of the trial anticipated in the middle of 2023 and the Phase 3 part of the trial anticipated in the middle of 2024.

We intend to conduct trials and pursue marketing authorizations with epetraborole in additional geographies outside of the United States and Europe, with an initial focus in Japan. We estimate that there are approximately 220,000 patients with NTM lung disease and approximately 21,000 patients with treatment-refractory MAC lung disease in Japan. We have initiated discussions with the Pharmaceutical and Medical Devices Agency, or PMDA, to gain alignment on the development plan necessary for regulatory approval of epetraborole in MAC lung disease. Our initial planned indication in all geographies is the treatment of patients with treatment-refractory MAC lung disease. We also intend to expand the indication targeted by epetraborole by pursuing development in other mycobacterial diseases, including treatment-naïve MAC lung disease, which development we believe is supportable by interim data received from the Phase 1b study and our existing nonclinical data package, and in *Mycobacterium abscessus, or M. abscessus*, lung infections, which is also supported by the interim data from the Phase 1b study, but for which additional nonclinical work may be needed. Additionally, we have a strategic partnership with Brii Biosciences Limited, or Brii Biosciences, under which we have licensed out our rights to develop, manufacture, and commercialize epetraborole in China, Hong Kong, Taiwan, and Macau.

The AN2 team has a deep expertise in boron chemistry as exemplified by our management team's history, 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 in NTM lung disease and other rare and chronic infectious diseases. We are also selectively evaluating in-licensing opportunities of development-stage candidates that have the potential to address rare and chronic infectious diseases consistent with our corporate strategy.

Our mission is to develop novel therapeutics to treat rare, chronic, and serious infectious diseases in areas of high unmet medical need. As leaders in the field of antimicrobials, we have both an obligation and a strong desire to combine our drug discovery and development expertise with resources available from public and private organizations to address high unmet needs in global health. To this end, in addition to the treatment of NTM lung disease, we are seeking non-dilutive funding to develop epetraborole for melioidosis, a disease that causes significant morbidity and mortality globally.

Our Team

Our team is led by Eric Easom, M.B.A., M.Eng., our co-founder, president, and chief executive officer. Mr. Easom has over 31 years of leadership experience in the biotechnology and pharmaceutical industry, including the last 15 years in infectious disease. He previously led Anacor's research and development efforts in global health. Paul Eckburg, M.D., our chief medical officer, previously served as chief medical officer at a number of other biotechnology companies and was involved in the development of multiple approved antibiotics. Sanjay Chanda, Ph.D., our chief development officer, previously served as chief development officer at Tioma Therapeutics, Inc. and was senior vice president of drug development at Anacor. Lucy Day, our chief financial officer, previously served as chief financial officer at Anacor. Kevin Krause, M.B.A., our chief strategy officer, previously served in various roles at Achaogen, Inc., Cerexa, Inc., and Theravance, Inc. and has deep expertise in antibiotic research, development, and commercialization. Our team also includes George Talbot, M.D., FACP, FIDSA, our co-founder and clinical advisor, Joseph Zakrzewski, our co-founder and chairman of the board of directors, and two inventors of epetraborole, Vincent Hernandez, our vice president of chemistry and Michael R.K. (Dickon) Alley, Ph.D., our head of biology and co-founder.

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:

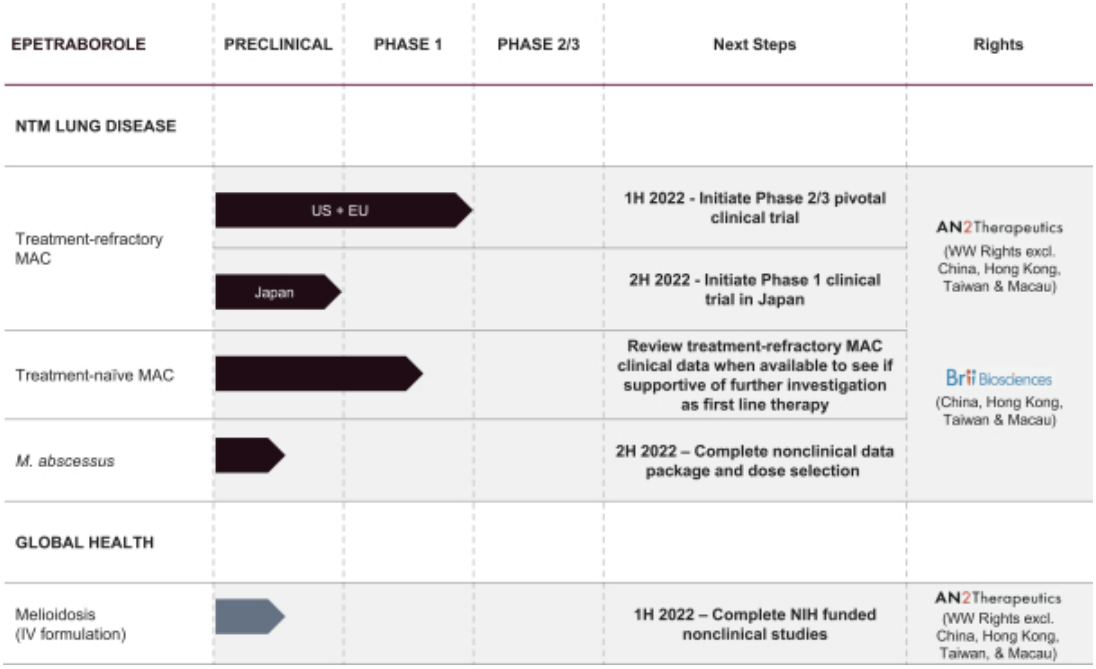
- **Advance epetraborole through clinical development in MAC lung disease with an initial focus on patients with treatment-refractory MAC lung disease.** We believe that epetraborole has a high potential to bring therapeutic benefit to patients with treatment-refractory MAC lung disease. We recently received clearance of our IND application by the FDA, have initiated pre-trial activities for our planned Phase 2/3 pivotal clinical trial, and anticipate initiating enrollment of patients in this trial in the first half of 2022 with topline results for the Phase 2 part of the trial anticipated in the middle of 2023 and the Phase 3 part of the trial anticipated in the middle of 2024. Based on our discussions with the FDA, we believe this Phase 2/3 pivotal clinical trial has the potential to be sufficient for regulatory approval in the United States and we intend to pursue regulatory approvals in the United States and Europe.
- **Develop epetraborole in additional territories and indications.** The number of cases of NTM lung disease 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 this particular geography, we intend to conduct clinical trials and pursue regulatory approval in Japan and more widely in Asia. We believe epetraborole has the potential to meet the ideal target product profile for treatment-naïve NTM lung disease caused by MAC due to its once-daily, oral dosing and recently received interim data from the Phase 1b study. 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 market potential, we intend to pursue development in both of these indications.
- **Build and scale organizational capabilities to support commercialization of epetraborole in MAC lung disease.** We have in-licensed the exclusive worldwide development and commercialization rights for epetraborole, and have licensed out our rights and entered into a strategic partnership with Brii Biosciences in China, Hong Kong, Taiwan, and Macau. We plan to build a specialized commercial organization to launch epetraborole in the United States and other key markets, including Japan, if approved. Within certain ex-U.S. and Japan markets, we may consider strategic collaborations for commercialization.
- **Continue to invest in expanding our pipeline of product candidates.** We have several preclinical programs targeting the development of novel antimicrobial compounds based on boron chemistry technology. We anticipate that these compounds will have the potential to be developed in combination with epetraborole for the treatment of NTM lung disease and other rare or chronic infectious diseases. We are also actively pursuing in-licensing of other compounds that are complementary to our strategy.
- **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. We intend to collaborate with both public and private organizations and foundations and seek non-dilutive capital to advance these global health initiatives.

Our Pipeline

We are initially focused on advancing our first product candidate, epetraborole, to commercialization in NTM lung disease. We are developing epetraborole to treat the most common type of NTM, MAC, which accounts for approximately 80% of NTM lung disease. We have in-licensed the exclusive

worldwide development and commercialization rights for epetraborole. We also have a strategic partnership with Brii Biosciences to develop epetraborole in China, Hong Kong, Taiwan, and Macau. In addition to our development and commercial endeavors in NTM lung disease, we intend to develop epetraborole for several global health initiatives, including melioidosis, using non-dilutive funding, which we plan to obtain from sources such as public and private agencies and foundations. We have entered into an Amended and Restated Global Health Agreement, or the Global Health Agreement, with Adjuvant Global Health Technology Fund L.P. and Adjuvant Global Health Technology Fund DE L.P., or together, Adjuvant, in connection with Adjuvant's investment of $12.0 million in our Series A and Series B redeemable convertible preferred stock financings. Pursuant to the Global Health Agreement, we must use reasonably diligent endeavors to develop epetraborole for melioidosis, tuberculosis, and any other mutually agreed-upon products for at-risk developing countries. We have entered into a research agreement with the National Institutes of Health, or NIH, to further early development and dose selection of epetraborole in melioidosis using in vitro hollow-fiber studies. These studies are being conducted at no cost to us. We believe partnerships like this provide substantial technical and capital resources to advance the melioidosis programs and provide material benefits to our company and to our NTM program as a whole.

The below table summarizes our development plans for epetraborole:



Our AN2 Drug Discovery Platform

Boron-Based Chemistry Enables the Targeting of Novel Biological Targets

Our core technology approach is based on the use of boron chemistry for our research and development initiatives. Boron has both a distinctive 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.

Boron chemistry has proven to be a highly productive technology leading to the discovery of many promising drugs, particularly focused in infectious diseases. Pioneering 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. One of these compounds, tavaborole, targets a fungal aminoacyl tRNA synthetase and is FDA-approved as Kerydin to treat onychomycosis of the toenails. Our lead compound, epetraborole, is a boron-containing analog of tavaborole and is designed to target bacterial leucyl-tRNA synthetase.

Targeting Bacterial Aminoacyl-tRNA Synthetases with Boron Containing Molecules

Aminoacyl-tRNA synthetases, or aaRSs, are enzymes that catalyze an essential step in protein synthesis—the attachment of amino acids to their corresponding tRNAs. These enzymes represent a promising set of targets for the development of new antibiotic drugs because of both their universal presence in bacteria and the significant structural and biochemical differences between bacterial and mammalian enzymes. These species-level differences allow for the design of selective inhibitors of bacterial enzymes that prevent bacterial protein synthesis without interfering with host protein synthesis.

With a few exceptions, each aaRS enzyme recognizes a single amino acid and attaches it to a corresponding tRNA that contains a specific three nucleotide sequence called an anticodon. This anticodon matches one or more corresponding three nucleotide sequences called codons in messenger RNA, or mRNA, that specify the addition of that specific amino acid in a growing protein chain. Each aaRS carries out a multi-step process: recognition of the correct amino acid, reaction of that amino acid with ATP to form a covalent intermediate referred to as an aminoacyl-adenylate, recognition of the tRNA, and reaction of the aminoacyl-adenylate with tRNA resulting in covalent attachment of the aminoacyl group to the tRNA and shutdown of the enzyme. The high fidelity of protein synthesis is maintained by stringent error-proofing functions of aaRS enzymes. This error-proofing takes place at several levels. The first level of specificity is controlled at the steps that involve the recognition of the amino acids and tRNA molecules and their covalent attachment. An additional level of specificity is obtained after the attachment, which in some aaRS enzymes occurs at an independent proof-reading or editing site on the same enzyme. When mismatched aminoacyl-tRNA molecules bind to this site, the aminoacyl group is removed and the tRNA molecule can be recycled.

The aaRS enzymes represent validated antibacterial targets but the properties of previous aaRS inhibitors have often limited their potential, especially inhibitors that target the aminoacylation site as they are often antagonized by the aaRS's cognant amino acid, thereby limiting their systemic efficacy. In addition, high protein binding and metabolic instability, as exemplified by mupirocin, an isoleucyl-tRNA synthetase inhibitor, can limit these inhibitors' clinical use to topical treatment of staphylococcal and streptococcal skin infections. These hurdles are largely removed by the oxaborole-tRNA trapping, or OBORT, inhibitors. These molecules are non-competitive inhibitors of aminoacylation where the boron molecule effectively recruits tRNA to become part of the inhibitor complex. As shown in Figure 1 below, this property enables a small polar molecule, similar in size to an amino acid, to become a potent enzyme inhibitor.

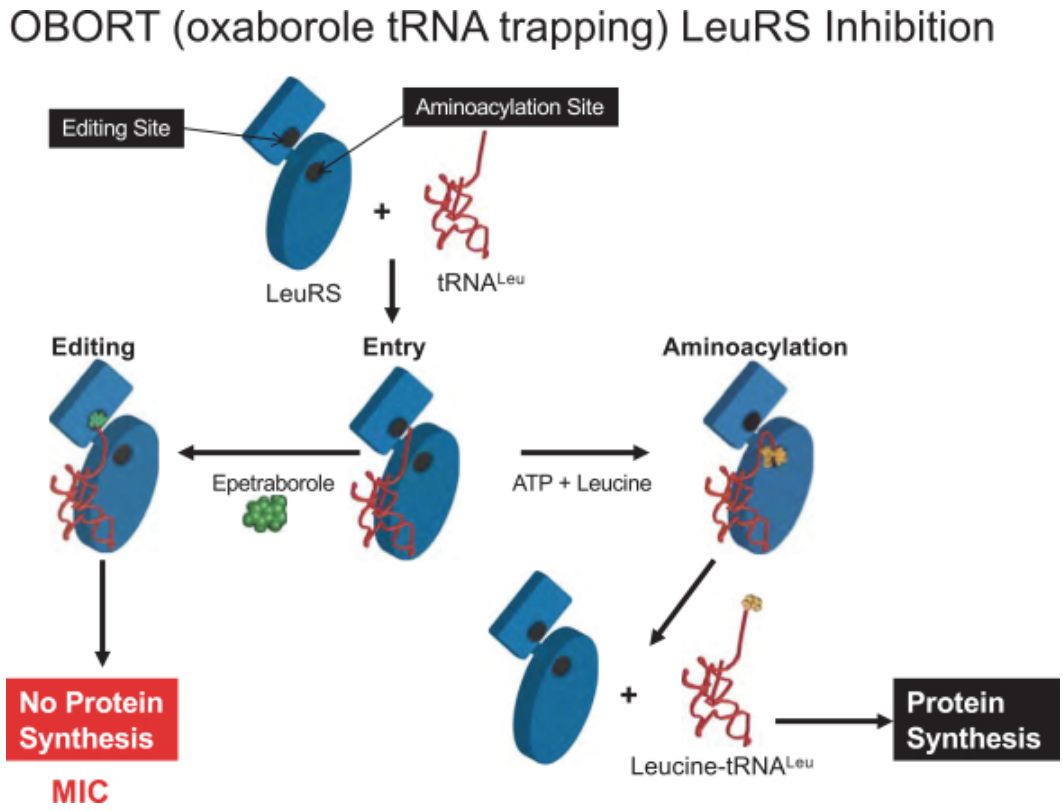


Figure 1. OBORT inhibitor (epetraborole) binds to the terminal adenosine ribose of $tRNA^{Leu}$ trapping it in the editing conformation thus inhibiting $tRNA^{Leu}$ leucylation in the aminoacylation site by leucyl-tRNA synthetase (LeuRS) using ATP+Leucine.

NTM Lung Disease Overview

Background

NTM lung disease is a rare, chronic, and progressive infectious disease caused by bacteria known as mycobacteria that lead to irreversible lung damage and can be fatal. The mycobacteria causing NTM lung disease are ubiquitous environmental organisms in water and soil; however, most people do not become sick when exposed to these bacteria. NTM is not transmitted from person-to-person, unlike infections with other species of mycobacteria, such as *M. tuberculosis*. People with underlying lung

conditions such as bronchiectasis, chronic obstructive pulmonary disease; cystic fibrosis; or a weakened immune system are predisposed to developing NTM lung disease, but for many patients it is not understood why they contract the disease.

The most common symptoms in individuals with NTM lung disease are similar to those in other respiratory infections and include cough, fatigue, shortness of breath, coughing up of blood, excessive mucus production, fever, night sweats, loss of appetite, and unintended weight loss. Wheezing and chest pain may also occur. Unlike most other respiratory infections, NTM causes a chronic infection that progresses to fibrosis, permanent lung damage, and respiratory failure. The diagnosis of NTM lung disease is based on a combination of clinical (e.g., pulmonary symptoms), radiographic (e.g., nodular or cavitary findings on chest radiograph), and microbiologic (e.g., positive sputum culture for pathogenic NTM) criteria. Approximately 80% of cases of NTM lung disease are caused by species within MAC (this complex includes *M. avium*, *M. intracellulare*, *M. chimaera*, and other related species). NTM is most common in women and individuals over the age of 65. The five-year mortality rate of patients with NTM lung disease ranges between 10% and 48% across multiple published studies.

The incidence of NTM lung disease is increasing in the U.S.by an estimated 8% per year. There are an estimated 200,000 patients with NTM lung infections in the United States, yet only approximately 55,000 are diagnosed. Underdiagnosis or delayed diagnosis has been identified as a key challenge in the management of NTM lung disease, due to lack of clinical suspicion, nonspecific respiratory symptoms, and underlying lung diseases that are frequent in patients with this infection. Among patients diagnosed with NTM lung disease, approximately 44,000 patients have MAC lung disease and approximately 35% of these patients, or 15,000 patients, have treatment-refractory MAC lung disease. There are approximately 20,000 total NTM patients in Europe, of which 5,600 are estimated to have treatment-refractory MAC lung disease.

Current Treatments

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, NTM infections require prolonged treatments, often for 18 months or longer. This extended dosing period increases the potential for antibiotic resistance to develop. Therefore, the first-line treatment for NTM is recommended to be a combination of three antibiotics that have non-overlapping mechanisms of action to reduce the emergence of resistance. A typical initial drug regimen for a patient with treatment-naïve NTM lung infection includes a macrolide such as clarithromycin or azithromycin that inhibits protein synthesis; ethambutol, an inhibitor of mycobacterial cell wall synthesis; and rifamycin, an inhibitor of RNA transcription. Use of these drugs is associated with the risks of developing side effects such as liver toxicity, ocular toxicity, and gastrointestinal intolerability as well as drug-drug interactions. Across multiple studies, treatment-emergent adverse effects occur in up to 70% of patients. As a result of these treatment-emergent adverse events, between 30% and 70% of patients receiving daily antimycobacterial therapy permanently discontinue at least one drug in their regimen.

As outlined in Figure 2 below, the current standard of care combination therapy for treatment-naïve patients is approximately 65% effective as determined by the ability to eliminate mycobacteria from sputum, defined as culture conversion by month six or three consecutive culture conversions measured once per month. Patients that do not culture convert after six months on standard of care treatment are then classified as treatment-refractory. Treatment-refractory patients are treated with increased frequency of dosing (daily vs. thrice weekly) of their previous combination therapies with the potential addition of new agents to the drug combination. The only FDA-approved drug for these patients is Arikayce, an inhaled liposomal formulation of amikacin, an IV-only protein synthesis inhibitor that has been commercially available since the 1970s. Treatment with Arikayce on top of the standard of care combination therapy increased the response rate (culture conversion) at six months to 29% compared to 9% for standard of care alone.

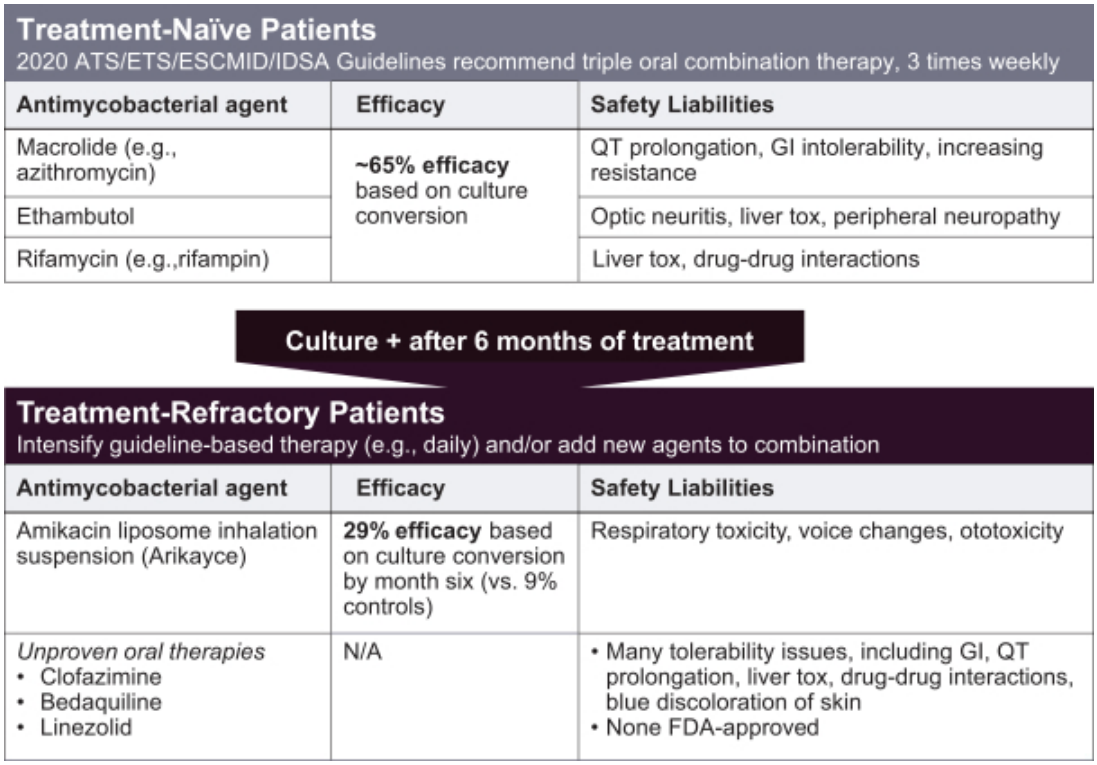


Figure 2. Treatment regimen for patients with NTM lung disease

Arikayce is associated with its own side effects including a number of warnings and precautions, adverse reactions, and a boxed warning that states “Arikayce has been associated with a risk of increased respiratory adverse reactions, including hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease that have led to hospitalizations in some cases.” As shown in Table 1 below, ototoxicity, including deafness, dizziness, presyncope, tinnitus, and vertigo, was reported in 17% of patients treated with Arikayce plus standard of care compared to 9.8% of patients treated with standard of care alone. This is a well-described class effect of aminoglycosides, including amikacin. Between 20.3% and 33.5% of patients treated with Arikayce in clinical trials discontinued treatment compared to between 0% and 8% of patients on standard of care alone. Despite these shortcomings, Insmed reported net sales of Arikayce of over $160 million in the United States in 2020, only its second year on the market.

Arikayce Pivotal Results Study Parameter	Arikayce	Control
Efficacy		
Culture-converted by month six	**29%**	9%
Safety		
Withdrawn from study	**20%**	9%
Upper respiratory adverse events	**18%**	2%
Ototoxicity	**17%**	10%

Table 1. Arikayce is associated with a high discontinuation rate and increased adverse events versus standard of care therapy alone.

Given the limitations of current standard of care regimens and Arikayce in treatment-refractory NTM lung disease caused by MAC, we believe that NTM lung disease is an indication with a continued high unmet medical need. NTM lung disease will likely continue to be treated in combination with the current standard of care. Therefore, there is a strong preference for novel antibiotics that can combine with existing drugs without significantly increasing the rate of adverse reactions. We believe improved treatment of NTM lung disease will require a safe and well-tolerated antibiotic that provides: a novel mechanism of action that is not affected by resistance to existing antibiotics; a convenient, once-daily, oral dose; and additional efficacy.

Our Solution: Epetraborole

We are developing epetraborole, an orally available small molecule inhibitor of bacterial leucyl-tRNA synthetase, or LeuRS, an enzyme involved in bacterial protein synthesis. 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 recently received clearance of our IND application by the FDA, and we anticipate initiating patient enrollment in a Phase 2/3 pivotal clinical trial of epetraborole in treatment-refractory MAC lung disease in the first half of 2022 with topline results for the Phase 2 part of the trial anticipated in the middle of 2023 and the Phase 3 part of the trial anticipated in the middle of 2024. We also believe epetraborole has the potential to meet the ideal target product profile for treatment-naïve NTM lung disease caused by MAC due to its once-daily, oral dosing and recently received interim data from the Phase 1b study. In addition, we believe that the broad antimycobacterial activity demonstrated by epetraborole in preclinical models may allow for its development in other infectious diseases caused by mycobacteria, including *M. abscessus* lung infections. To expand epetraborole's market potential, we intend to pursue development in both of these indications.

Key Attributes of Epetraborole

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 MAC lung disease and an attractive opportunity for a safe, tolerable, effective, and oral antibacterial drug that could significantly improve patient outcomes. For example, Arikayce, the only FDA approved therapy for treatment refractory MAC lung disease patients, had reported net sales of over $160 million in the United States in 2020, only its second year on the market, despite a boxed warning for severe respiratory adverse events.
- **Novel mechanism of action with a broad spectrum of antimycobacterial activity.** Epetraborole inhibits bacterial leucyl-tRNA synthetase, a bacterial target with a novel mechanism of action for which there are no approved drugs. Epetraborole has demonstrated broad antimycobacterial activity in preclinical models against MAC, including *M. avium*, *M. intracellulare*, and *M. chimaera*, which is the most common type 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.
- **Substantial clinical and non-clinical data package may support a streamlined development program.** Epetraborole has previously been investigated by Anacor and GSK in intravenous and oral formulations in six previous Phase 1 and two truncated Phase 2 clinical trials in over 200 subjects at a wide range of clinical doses. We have completed the Phase 1b dose-ranging study cohorts in healthy volunteers, in order to assess the pharmacokinetics and safety of oral epetraborole doses relevant for MAC and administered for 28 days, and have begun enrollment in the final, open label, food-effect cohort. Previously, epetraborole

pharmacokinetics, distribution, and metabolism were well characterized using substantially higher doses. Results from a Phase 1 clinical trial showed the exposures of epetraborole in alveolar (lung) macrophages, the 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. Furthermore, we have completed extensive toxicology and safety pharmacology studies, including chronic toxicology studies by oral administration in both rat (six months) and non-human primates (nine months) where epetraborole was tolerated at much higher exposures compared to the once-daily dose of 500 mg that we intend use to treat patients with NTM lung disease in our planned Phase 2/3 pivotal clinical trial. Lastly, we have successfully manufactured drug substance and drug product in large-scale batches.

- **Convenient once-daily, oral dosing with the aim to serve as an important component of therapy for MAC lung disease.** Epetraborole is an orally available drug intended to be dosed once-daily, thereby providing a convenient addition to standard of care therapy compared to drugs delivered by other methods such as nebulizers (e.g., Arikayce), injections, or intravenous infusions.
- **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 will develop. Given epetraborole's novel mechanism of action and low potential for drug-drug interactions with existing antibiotics that would limit its ability to be added to standard of care combination regimens, epetraborole, if approved, has the potential to become an important component of a multi-drug treatment regimen for patients suffering from MAC lung disease. We believe that the attributes of epetraborole are aligned with the unmet need in treatment-refractory MAC lung disease and compare favorably to Arikayce, which is the only currently approved therapy for patients with this condition, and product candidates SPR-720, which is being developed by Spero Therapeutics, Inc., and RHB-204, which is being developed by Redhill Biopharma Ltd. For example, Arikayce has a boxed warning for severe respiratory adverse events, and both SPR-720 and RHB-204 are currently being developed for treatment-naïve patients.

Mechanism of Action

Epetraborole is a small molecule inhibitor of bacterial LeuRS, an aaRS enzyme, which catalyzes an essential step in protein synthesis. As shown in Figure 3 below, epetraborole forms a complex with a leucyl tRNA molecule, trapping the tRNA molecule in the editing site of the enzyme, which prevents the synthetic site from attaching leucine to tRNA thus shutting down tRNA leucylation and leading to a block in protein synthesis.

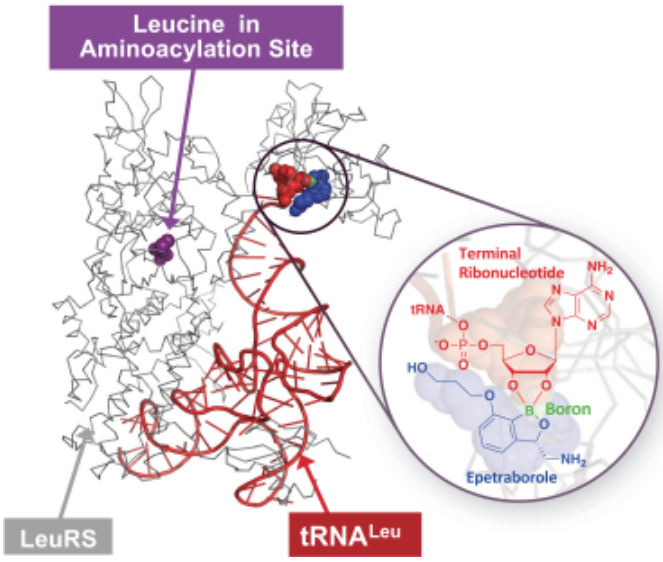


Figure 3. Epetraborole inhibits the protein synthesis enzyme leucyl-tRNA synthetase (LeuRS) by binding to the terminal adenosine ribose of $tRNA^{Leu}$ in the editing site.

Properties of Epetraborole

Broad Antimicrobial Activity

As shown in Table 2 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 2. Antimicrobial activity of epetraborole, clarithromycin and amikacin against 51 isolates of MAC including 17 *M. intracellulare* isolates, 1 *M. avium* isolates, 3 *M. avium* complex isolates, 20 *M. avium* subsp. *hominissuis* isolates, and 10 *M. chimaera* isolates

Epetraborole is Highly Selective for Bacterial LeuRS

Humans have two LeuRS enzymes: a mitochondrial LeuRS and a cytoplasmic LeuRS. Although there is weak sequence similarity between mitochondrial LeuRS and bacterial LeuRS, the human mitochondrial enzyme lacks a functional editing site. Research published by members of our founding team discovered that epetraborole was a poor inhibitor of human cytoplasmic LeuRS, with an IC_{50} of 185 µM and had virtually no activity against proliferation of a human liver cell line (>500 µM) when compared to the IC_{50} values of 0.12 and 0.25 µM measured against bacterial forms of the enzyme in *Escherichia coli* and *Klebsiella pneumoniae*, respectively. We believe the mitochondrial LeuRS enzymes lack of an editing function and the weak binding to cytoplasmic LeuRS make epetraborole an

attractive candidate as an antibiotic because it suggests that it is not likely to significantly inhibit host protein synthesis at the same drug concentrations that completely inhibit bacterial LeuRS.

Linearity of Epetraborole Pharmacokinetics

Pharmacokinetic data from a prior Phase 1 SAD/MAD clinical trial of epetraborole conducted by GSK was used to establish the linear relationship between doses of 200 mg to 4,000 mg per day administered via IV (summarized in Figure 4 below). These results demonstrate the highly linear pharmacokinetic profile of epetraborole. In addition, doses up to 4,000 mg IV per day for 14 days were used, at exposures much higher than we believe are needed to treat patients with MAC lung disease. These data, in combination with other available human pharmacokinetic data, were used to establish a population pharmacokinetics model that can predict exposures between doses and subjects due to the pharmacokinetic linearity and substantially low inter-patient variability. We believe these data indicate that expected efficacious exposures can be achieved with our target doses.

Cohort	SAD 1	SAD 2	SAD 3	SAD 4	SAD 5	MAD 1	MAD 2	MAD 3	MAD 4
Dose (mg)	200	400	900	2000	3000	500	750	1200	2000
Frequency	x1	x1	x1	x1	x1	Q12h	Q12h	Q12h	Q12h
Duration (d)	1	1	1	1	1	8	14	14	14
AUC (h.µg/mL)	9.8	19	46	107	145	56	75	117	194
C_{max} (µg/mL)	2.9	5.9	14	32	42	9.4	12	19	31
CL (L/h)	18.0	18.5	17.2	16.5	18.4	15.3	19.4	18.1	18.1
$T_{1/2}$ (h)	10.9	11.3	10.8	11.2	10.4	10.7	10.6	10.5	10.0

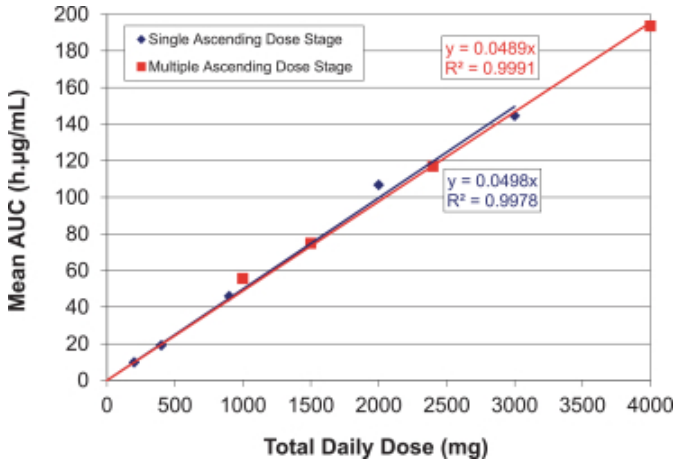


Figure 4. Pharmacokinetic data from a Phase 1 SAD/MAD clinical trial of epetraborole was used to establish the linear relationship between doses of 200 mg to 4,000 mg per day administered via IV.

Preclinical Experience for MAC

In vivo antibacterial activity of epetraborole has been demonstrated in the chronic mouse model of MAC lung disease. In this model, C57BL/6 mice were infected via aerosol with 10^{11} colony forming units, or CFU, per mouse of one of five different isolates of MAC: *M. avium* 2285 (R) (epetraborole MIC = 4 µg/mL); *M. avium* ATCC 700898 (epetraborole MIC = 2 µg/mL); *M. intracellulare* 1956 (epetraborole MIC = 2 µg/mL); *M. intracellulare* DNA00111 (epetraborole MIC = 8 µg/mL); or *M. intracellulare* DNA00055 (epetraborole MIC = 8 µg/mL). The higher MIC values for these isolates allows us to select a dose for our planned Phase 2/3 pivotal clinical trial that is expected to provide potentially efficacious clinical exposures against the full range of epetraborole MIC values (see Table 1). In these models, the infection was

allowed to proceed for 28 days before treatment was initiated, which approximates the human disease more closely than shorter mouse models as bacterial growth is largely stationary at initiation of dosing. Starting on day 28, mice were treated daily with orally administered antibacterial therapy for two months, after which the bacteria in lungs were plated on a media plate on day 84 to isolate the bacteria and to determine viable bacteria and CFUs.

Using this chronic mouse model of MAC lung disease and the biofilm forming isolate MAC, *M. avium* 2285 (R), an initial study was conducted using a range of oral doses from 1 to 500 mg/kg daily of epetraborole. This study showed improved antibacterial activity of epetraborole at all doses compared to the daily humanized clarithromycin dose of 250 mg/kg.

As shown in Figure 5 below, treatment with oral doses of 100 mg/kg (which is approximately equivalent to an oral human dose of 250 mg once-daily) reduced counts of viable *M. avium* 2285 (R) by >500-fold, or 2.7-$\log_{10}$. Doses of 200, 300, and 500 mg/kg (approximately equivalent to oral human doses of 650, 900, and 1500 mg once-daily, respectively) led to reduction in viable *M. avium* 2285(R) by 1,000-fold, or 3-$\log_{10}$. In addition, the lowest dose studied, 1 mg/kg (approximately equivalent to an oral human dose of 2 mg once-daily) produced a 250-fold, or 2.4-$\log_{10}$, reduction in viable bacteria, which was significantly better than clarithromycin treated animals at a p-value of 0.0007. No isolates with decreased susceptibility were found in any active epetraborole dosing group.

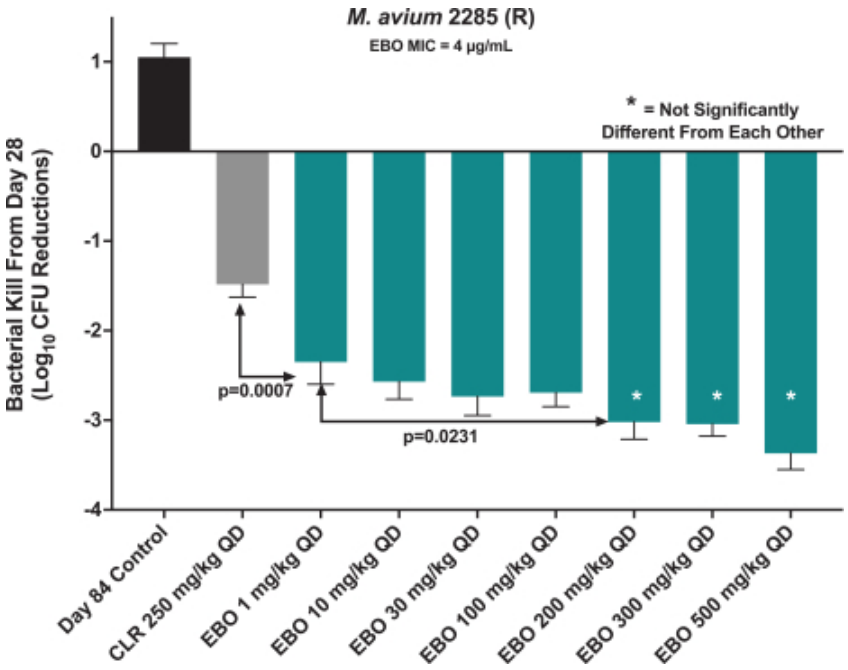


Figure 5. Epetraborole (EBO) and Clarithromycin (CLR) antibacterial activity in a chronic model of MAC lung disease in mice against *M. avium* 2285 (R).

These data were used to design subsequent experiments against the additional four isolates, which evaluated the activity of potential human equivalent doses using 100, 200, or 300 mg/kg epetraborole administered orally once-daily and 400 mg/kg epetraborole administered orally every other day. These active epetraborole treatment groups were compared against an untreated placebo control and the daily oral standard of care combination regimen of 250 mg/kg clarithromycin, 100 mg/kg ethambutol and 100 mg/kg rifabutin. We also tested whether the addition of 200 mg/kg epetraborole

on top of standard of care would improve the antibacterial activity of the once-daily standard of care regimen. This approach is consistent with our planned Phase 2/3 pivotal clinical trial.

Figure 6 shows the efficacy data for the other four isolates tested: *M. avium* ATCC 700898; *M. intracellulare* 1956; *M. intracellulare* DNA00111; and *M. intracellulare* DNA00055. A dose response was observed across the range of epetraborole doses studied, with all doses leading to at least a 100-fold, or 2-$\log_{10}$, reduction in viable bacteria for all isolates tested. Although the standard of care regimen led to a range of 1.7- to 4.2-$\log_{10}$ reductions in viable bacteria across the isolates tested, the addition of 200 mg/kg epetraborole (approximately equivalent to a 650 mg oral human equivalent dose based on area under the curve, or AUC, values from a human oral 500 mg dose) led to statistically significant reductions in viable bacterial colonies over the standard of care regimen alone with every strain tested. Reductions in viable bacteria for the standard of care plus epetraborole combination regimens ranged from 40,000 to 400,000-fold, or 4.6- to 5.6-$\log_{10}$, reductions in viable bacteria.

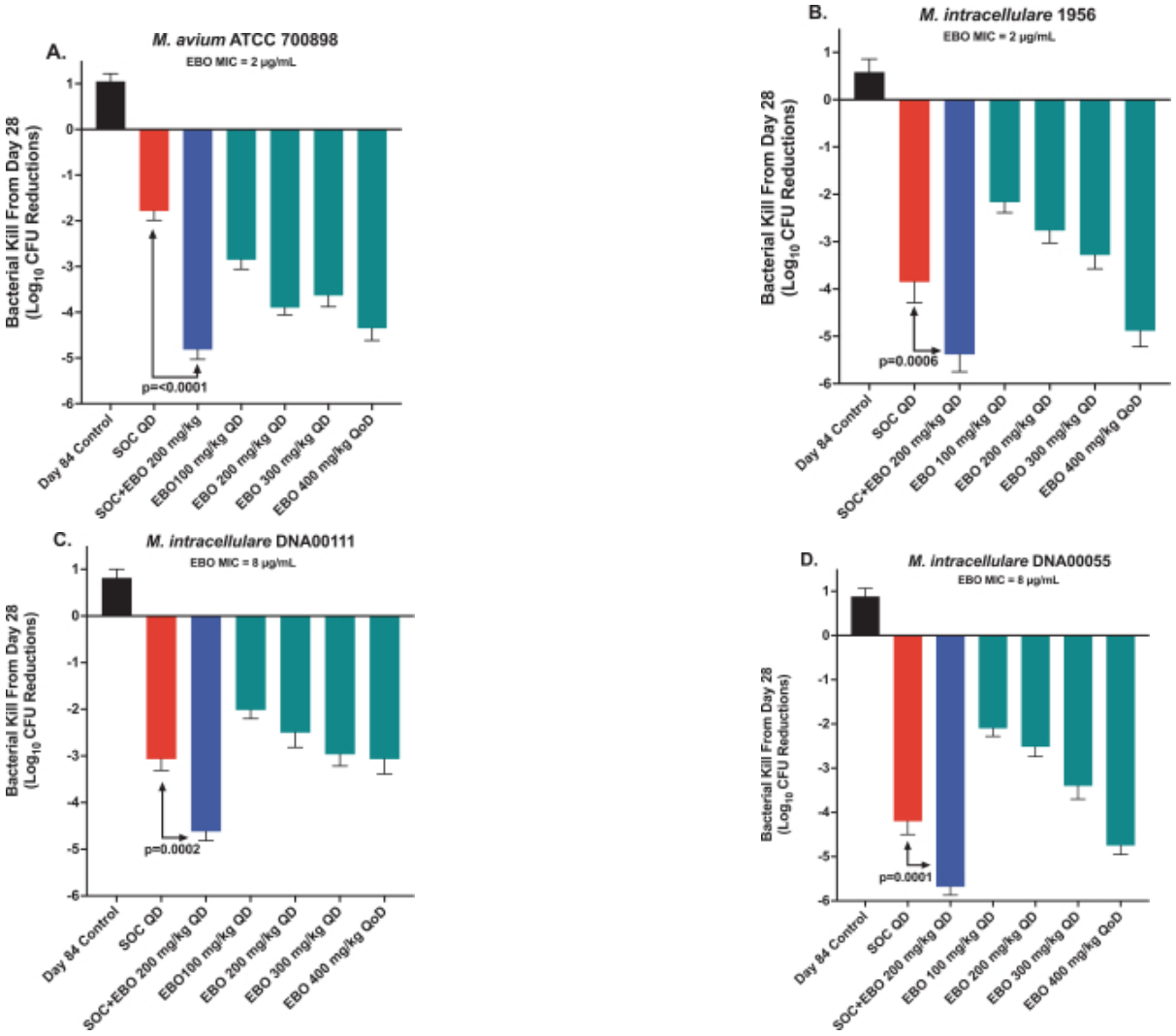


Figure 6. Epetraborole antibacterial activity in a chronic model of MAC lung disease in mice against *M. avium* ATCC 700898 (A), *M. intracellulare* 1956 (B), *M. intracellulare* DNA00111 (C), and *M. intracellulare* DNA00055 (D)

In summary, epetraborole monotherapy showed significant reductions in MAC CFUs, in some cases better than the triple-drug regimen. In every case, epetraborole on top of standard of care led to significant reductions in MAC CFUs.

Additionally, we assessed the potential for emergence of epetraborole resistance when dosed as monotherapy and the ability of combination regimens to suppress the emergence of epetraborole resistance in a hollow-fiber system MAC model, or HFS-MAC. The HFS model is routinely used in antibacterial development to study the pharmacodynamics of drugs using human simulated pharmacokinetics, as a tool for dose selection, and as a means to define drug exposures that lead to and prevent emergence of resistance. The HFS-MAC model is tailored for use against bacteria that reside within macrophages. Specifically, human THP-1 monocytes are infected with MAC and transferred into a hollow fiber system in which cultures could be maintained for periods of 28 days. Bacterial growth media flows through the system and antibacterial drug is titrated in to simulate the pharmacokinetics of that drug. The infected macrophages are contained within a porous “hollow-fiber” cartridge that retains the macrophages while allowing the growth media and drug to flow through the system. The cartridge contains a sampling port that allows for collection of bacteria over time throughout the experiment. We believe that there are four advantages of this HFS-MAC model to determine human doses, to suppress resistance, and to treat MAC lung disease:

- The HFS-MAC model mimics human infections in that MAC resides within human alveolar macrophages, which in this model are THP-1 cells;
- Human drug exposure can be replicated based on fluid flow through the HFS to help determine real-world target exposures in human pharmacokinetic experiments;
- The antibacterial effects of combination therapies can be assessed over a 28-day period; and
- The bacterial burden can be readily and repeatedly assessed to determine the kinetics of antibacterial activity and the rate of emergence of any drug resistant bacteria.

As illustrated in Figure 7 below, the results in this model showed treatment with epetraborole monotherapy led to a rapid 100-fold reduction in viable MAC within five days of treatment initiation and then plateaued after approximately ten days of dosing, which we believe is due most likely to the emergence of strains of *M. avium* that have developed resistance to epetraborole. This is an expected result that has been observed when all other antimycobacterial agents are used as monotherapy in this model. However, when epetraborole was dosed along with the standard of care combination therapy, no epetraborole resistance was observed.

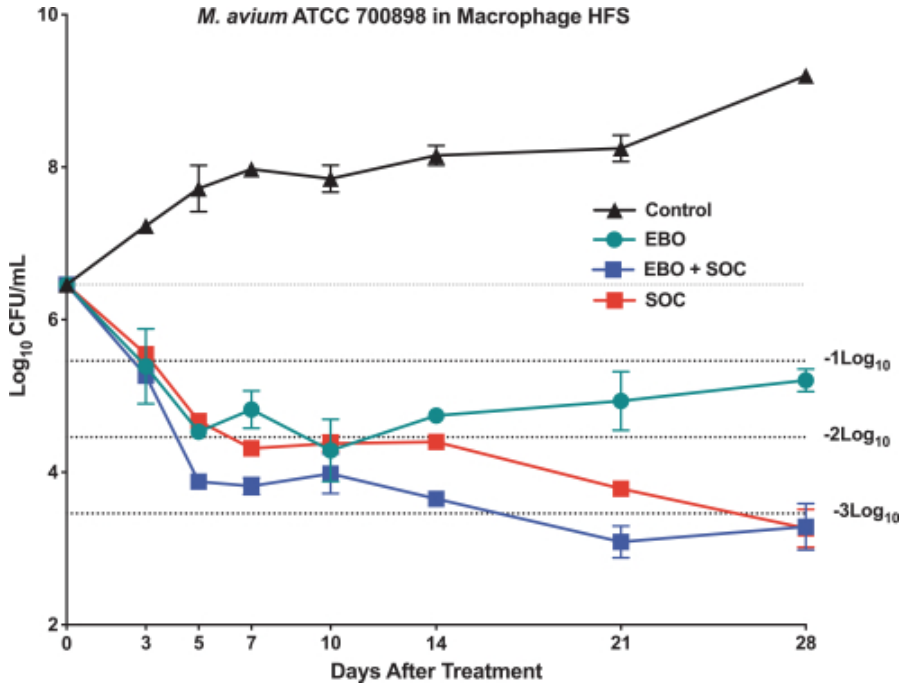


Figure 7. Epetraborole had antibacterial activity both as monotherapy and in combination therapy with a standard of care (clarithromycin, ethambutol, rifabutin) regimen in a HFS-MAC model.

Prior Clinical Experience with Epetraborole

Epetraborole was previously developed by Anacor and licensed by GlaxoSmithKline plc, or GSK, in 2010, where it was originally developed for the acute treatment of complicated urinary tract and intra-abdominal infections. Development of epetraborole was discontinued by GSK due to clinical resistance observed in four of 20 subjects enrolled in GSK's Phase 2 trial to evaluate epetraborole as a monotherapy in patients with complicated urinary tract infection, or cUTI, described below, which led GSK to return the molecule to Anacor. Clinical resistance occurs when bacteria, under drug pressure or through natural resistance, are increasingly not susceptible to an antibiotic. Clinical resistance is possible for all antibiotics and the rates and emergence of resistance vary by bacterial species. In the case of epetraborole, four resistant isolates (>32-fold decrease in susceptibility) emerged in the Phase 2 cUTI trial. No clinical resistance was observed in the other epetraborole trials conducted by GSK, including the complicated intra-abdominal infections, or cIAI, trial. Combination therapy has been shown to significantly reduce the risk of emergence of clinical resistance. NTM is treated with combination therapy per treatment guidelines. This is distinct from earlier clinical trials of epetraborole in other infection types where monotherapy epetraborole was evaluated.

Unlike cUTI and cIAI where monotherapy (a single drug) is standard of care, NTM lung disease is treated with combination therapy (multiple antibiotics used concurrently) consisting of different mechanisms of activity, per the treatment guidelines of the American Thoracic Society and the Infectious Diseases Society of America. Combination therapy is used to mitigate the development of clinical resistance, which is unavoidable with monotherapy antibiotic treatments. We believe that we can improve the treatment of patients with NTM lung disease with epetraborole as part of a combination therapy to avoid the development of clinical resistance. See "—Rationale for Use of Epetraborole in Treating NTM Lung Disease." We obtained an exclusive license to epetraborole from

Anacor in 2019 and initiated a Phase 1b dose-ranging study to evaluate oral dosing of epetraborole in healthy volunteers in 2021. Over 200 subjects were dosed with epetraborole at a wide range of clinical doses in one Phase 1 clinical trial conducted by Anacor and five Phase 1 clinical trials and two Phase 2 clinical trials conducted by GSK. Recently received interim data from our Phase 1b dose-ranging study (EBO-101) is expected to provide additional safety, tolerability, pharmacokinetics, and food effect data that we believe, together with the data from Anacor and GSK's prior clinical experience with epetraborole described in Table 3 below, will inform our dose selection for our Phase 2/3 clinical trial and any additional clinical trials in NTM patients.

Study Title	Patient Population	Epetraborole Formulation	Enrollment	Status
SAD/MAD (Anacor AN3365-PK-101) Phase 1 study to evaluate safety, tolerability, and pharmacokinetics of epetraborole	Healthy volunteers	Intravenous	72 participants total SAD: 40 (30 epetraborole) MAD: 32 (24 epetraborole)	Completed
Intrapulmonary PK (GSK LRS114926) Phase 1 study to evaluate serum and pulmonary pharmacokinetics of epetraborole	Healthy volunteers	Intravenous	30 participants total Single dose: 15 (15 epetraborole) q12h x 3 days: 15 (15 epetraborole)	Completed
Mass balance (GSK LRS115243) Phase 1 study to investigate recovery, excretion, and pharmacokinetics of epetraborole	Healthy volunteers	Intravenous	6 participants total Single dose: 6 (6 epetraborole)	Completed
SAD/MAD and supratherapeutic dose in Japanese subjects (GSK LRS116160) Phase 1 study to evaluate safety, tolerability, and pharmacokinetics of epetraborole	Healthy volunteers	Intravenous	8 participants total Single dose: 8 (8 epetraborole)	Terminated early due to results from study GSK LRS114688 Phase 2 trial
Complicated urinary tract infections (GSK LRS114688) Phase 2 study of safety, tolerability, and efficacy of epetraborole compared to imipenem-cilastatin	Patients with acute complicated urinary tract infection and acute pyelonephritis	Intravenous	20 patients total Multiple dose: 20 (14 epetraborole)	Terminated due to microbiological findings of resistance
Complicated intra-abdominal infections (GSK LRS114689) Phase 2 study of safety, tolerability, and preliminary efficacy of epetraborole compared to meropenem	Patients with complicated intra-abdominal infection	Intravenous	15 patients Multiple dose: 15 (9 epetraborole)	Terminated early due to results from study GSK LRS114688 Phase 2 trial

Study Title	Patient Population	Epetraborole Formulation	Enrollment	Status
		Total enrollment with intravenous formulation:	**151 (121 epetraborole)**	
SAD/MAD (GSK LRS114470) Phase 1 study to evaluate safety, tolerability, and pharmacokinetics of epetraborole	Healthy volunteers	Oral	77 participants total SAD: 22 (18 epetraborole) MAD: 55 (41 epetraborole)	Terminated early due to tolerability issues at 3,000 mg twice-daily dose level
Food effect (GSK LRS115244) Phase 1 study to investigate relative bioavailability, safety, and tolerability of various oral formulations of epetraborole	Healthy volunteers	Oral	24 participants total Single dose: 24 (24 epetraborole)	Terminated early due to results from study GSK LRS114688 Phase 2 trial
		Total enrollment with oral formulation:	**101 (83 epetraborole)**	
		Total enrollment (combined intravenous plus oral formulation):	**252 (204 epetraborole)**	

Table 3. Summary of prior clinical studies conducted by Anacor and GSK for evaluating epetraborole

SAD/MAD (Anacor AN3365-PK-101)—Phase 1 Study to Evaluate Safety, Tolerability, and Pharmacokinetics of Intravenous Epetraborole

Anacor previously conducted a first-in-human Phase 1 single ascending and multiple ascending dose study to evaluate the safety, pharmacokinetics, and tolerability of intravenous administration of epetraborole (AN3365) in healthy volunteers. The study enrolled 40 participants in a single ascending dose arm, with 30 subjects receiving epetraborole at doses ranging from 200 mg to 3,000 mg, and 32 participants in a multiple ascending dose arm, with 24 subjects receiving epetraborole twice-daily doses ranging from 500 mg to 2,000 mg for 14 days.

In the single ascending dose arm, the study found that following administration as a one-hour infusion, AUC and maximum concentration, or C_{max}, of epetraborole were approximately dose proportional after both single and repeat dosing. Mean $AUC_{0-¥}$ and C_{max} values after the highest single dose administered (3,000 mg) were 145 µg·h/mL and 42 µg/mL. In the multiple ascending dose arm, mean AUC_{0-12} and C_{max} values after the highest repeat dose regimen (2,000 mg) were 97 µg·h/mL and 31 µg/mL. No unexpected accumulation was observed after twice-daily dosing for up to 14 days, indicating no time-dependent changes in pharmacokinetics.

There were no deaths, serious adverse events, or SAEs, or any adverse events, or AEs, leading to withdrawal from the study. The three most common AEs reported in the trial were headache, postural hypotension, and cannulation site injury. There was no apparent dose response to these AEs and all were observed in placebo subjects. In both arms of the study, no clinically significant abnormalities were reported in laboratory values after administrations of intravenous epetraborole; however, variable decreases in reticulocyte counts and hemoglobin levels were observed, which were not considered treatment-emergent AEs by the investigator.

Intrapulmonary Pharmacokinetics (GSK LRS114926)—Phase 1 Study to Evaluate Serum and Pulmonary Pharmacokinetics of Intravenous Epetraborole

GSK previously conducted a Phase 1 parallel-cohort study to evaluate the safety, tolerability, and plasma and intrapulmonary pharmacokinetics of intravenous administration of epetraborole (GSK2251052) in healthy volunteers. The study enrolled 15 participants in a single dose cohort of 1,500 mg and 15 participants in a multiple dose arm of 1,500 mg twice-daily for three days.

Results of the study showed that exposures of epetraborole were five times higher in lung macrophages than in plasma. Because lung macrophages are the cells that are infected with MAC, we believe the ability of epetraborole to selectively reach these higher exposures in alveolar macrophages position the treatment of NTM lung disease as an attractive indication for development of epetraborole. Figure 8 below summarizes the exposures of epetraborole in plasma and alveolar macrophages observed in the study.

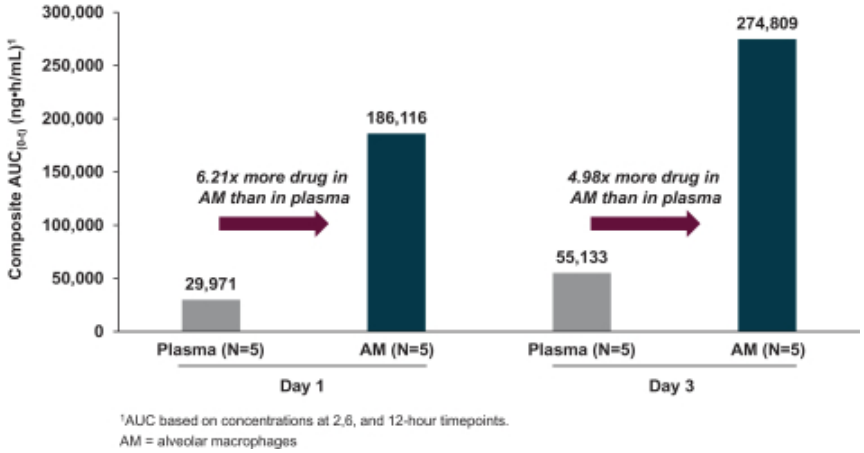


Figure 8. Intravenous dosing of epetraborole led to five times higher levels of the drug in alveolar macrophages than in plasma.

Results in the study indicated that following administration of 1,500 mg epetraborole via IV infusion, epetraborole was eliminated slowly with a median half-life value of 10.7 hours. On average, systemic clearance was low: approximately 23.1 L/h on day one and 20.6 L/h on day three. The fraction of unchanged epetraborole recovered in urine after 48 hours was approximately 26.8% of the total administered dose. The mean steady state volume of distribution, or V_{SS}, (approximately 231 L) exceeded the total body water and total body weight of a 70 kg human, indicating that epetraborole was highly distributed in tissues. In the single dose cohort, the epetraborole concentrations in alveolar macrophages relative to those in plasma were 621% based on composite AUC and, on average, 573%, 726%, and 544% at the 2-, 6-, and 12-h BAL sampling points, respectively, relative to the concentrations in plasma following a single dose and 498% based on composite AUC and, on average, 549%, 405%, and 566%, at the 2-, 6-, and 12-h BAL sampling points, respectively, relative to the concentrations in plasma following multiple doses.

There were no SAEs or other AEs leading to withdrawal from the study. The most common drug-related AE was infusion site reactions in six subjects, followed by chest pain, dizziness, and orthostatic hypotension in two subjects or fewer.

Mass Balance (GSK LRS115243)—Phase 1 Study to Investigate Recovery, Excretion, and Pharmacokinetics of Intravenous Epetraborole

GSK previously conducted a Phase 1 mass balance study to evaluate the recovery, excretion and pharmacokinetics of intravenous administration of epetraborole (GSK2251052) in healthy volunteers. The study enrolled six participants in a single dose cohort to receive a single intravenous dose of 1,500 mg of epetraborole containing a small amount of a radioactive radiolabel isotope to follow the absorption, metabolization, and excretion process.

The results indicated that following administration of 1,500 mg epetraborole with the radiolabel via intravenous infusion, radiocarbon was slowly eliminated from plasma with a mean half-life of 96 hours. The mean half-life observed in whole blood was 14.3 hours. Total radioactivity was highly distributed in tissues, based on the mean V_{SS} of radiocarbon in plasma (348 L). The mean $AUC_{0-¥}$ values for epetraborole and metabolite M3 were 37% and 53% of the radiocarbon $AUC_{0-¥}$ value observed in plasma, respectively, indicating that the majority of plasma radioactivity is accounted for by the parent epetraborole and the metabolite M3.

There were no SAEs and only mild treatment-emergent AEs were observed, but none were considered related to epetraborole. There were no severe or serious adverse events or withdrawals from the study drug due to an AE, and no clinically significant changes in vital signs were observed.

SAD/MAD and Supratherapeutic Dose in Japanese Subjects (GSK LRS116160)—Phase 1 Study to Evaluate Safety, Tolerability, and Pharmacokinetics of Epetraborole

GSK previously initiated a Phase 1 study to evaluate the safety, tolerability, and pharmacokinetics of intravenous administration of epetraborole (GSK2251052) in healthy Japanese and Caucasian volunteers. The study was designed to enroll a single ascending dose arm and a multiple ascending dose arm in several genotype groups; however, the first portion was only partially completed before the study was terminated early based on emerging data from the Phase 2 cUTI trial described below. The study enrolled eight Japanese participants receiving epetraborole in single doses of 750 mg or 1,500 mg before early termination of the study. Among the eight subjects enrolled, the plasma pharmacokinetics and tolerability of single doses of intravenous administration of epetraborole were generally consistent with those previously reported in the Anacor Phase 1 study described above.

There were no SAEs or drug-related AEs or withdrawals from the study drug due to an AE.

Complicated Urinary Tract Infections (GSK LRS114688)—Phase 2 Study of Safety, Tolerability, and Preliminary Efficacy of Epetraborole Compared to Imipenem-Cilastatin

GSK previously initiated a Phase 2 trial to evaluate the safety, tolerability, pharmacokinetics, and efficacy of intravenous administration of epetraborole (GSK2251052) compared to imipenem-cilastatin in adult patients with cUTI, including acute pyelonephritis. The trial enrolled a total of 20 patients, with six patients treated with epetraborole at a dose of 750 mg, eight patients treated with epetraborole at a dose of 1,500 mg and six patients treated with imipenem-cilastatin.

After the first 20 patients were enrolled, the trial was terminated early after four urine culture isolates (*E. coli x2, P. mirabilis,* and *K. pneumoniae*) demonstrated a significant increase (³32-fold) in epetraborole MIC between baseline and day two. Sequencing analysis of *leuS* from the isolates showed that the baseline isolates were found to have no mutations in *leuS*, and post-baseline isolates were found to contain either single or double editing domain mutations in *leuS*. No other significant changes in the susceptibility of tested comparators were observed.

Emergence of epetraborole resistance was observed in four of 20 subjects enrolled in this Phase 2 cUTI trial, which led GSK to discontinue development of epetraborole for complicated gram-negative bacterial infections and to return the molecule to Anacor. Rifampicin, when studied in a monotherapy cUTI trial, showed similar to greater development of clinical resistance, which was ablated by the addition of another active drug, trimethoprim. In addition, rifampicin has been a frontline agent in treating NTM lung disease and tuberculosis for decades.

Sixteen of 20 patients reported AEs; nausea, increased alanine aminotransferase, and dizziness were the most commonly reported. SAEs of aspiration bronchial, hemoglobin decrease, cardiac arrest, *Escherichia* bacteremia, and pulmonary embolism were observed in three patients treated with epetraborole. The SAEs of hemoglobin decrease and *Escherichia* bacteremia were considered related to epetraborole.

Complicated Intra-Abdominal Infections (GSK LRS114689)—Phase 2 Study of Safety, Tolerability, and Preliminary Efficacy of Intravenous Epetraborole Compared to Meropenem

GSK previously initiated a Phase 2 trial to evaluate the safety, tolerability, pharmacokinetics, and efficacy of intravenous administration of epetraborole (GSK2251052) compared to meropenem in adult patients with complicated intra-abdominal infections. The trial enrolled a total of 14 patients, with five patients treated with epetraborole at a dose of 750 mg, four patients treated with epetraborole at a dose of 1,500 mg and five patients treated with 1,000 mg of meropenem. After the first 14 patients were enrolled, the trial was terminated early because of emergent bacterial resistance in the Phase 2 trial in cUTIs, as described above.

Twelve of 15 subjects reported AEs; diarrhea and pyrexia were the most common AEs reported. SAEs of abdominal abscess, pelvic abscess, blood creatinine increase, hemoglobin decrease, acute pancreatitis, and bile duct stone were observed in three patients treated with epetraborole, although no SAEs were considered related to epetraborole.

SAD/MAD (GSK LRS114470)—Phase 1 Study to Evaluate Safety, Tolerability, and Pharmacokinetics of Oral Epetraborole

GSK previously conducted a Phase 1 dose escalation study to evaluate the safety, tolerability and pharmacokinetics of orally administered epetraborole (GSK2251052) in healthy volunteers. Epetraborole was administered as either tablets or as an oral solution. The study enrolled 22 participants in a single ascending dose arm, with 18 subjects receiving epetraborole at doses ranging from 500 mg to 4,000 mg, and 55 participants in a multiple ascending dose arm, with 41 subjects receiving epetraborole at daily doses ranging from 4,000 mg to 6,000 mg for ten days as 2,000 mg administered in twice- or thrice-daily dosages.

In the single ascending dose arm, results indicated dose proportionality over the doses used in the study. Following single-dose administration of oral epetraborole as 500 mg, 2,000 mg, and 4,000 mg oral tablets in the fasted state, AUC and C_{max} increased with dose. The half-life was approximately ten hours. AUC and C_{max} exhibited low to moderate inter-subject variability. In the multiple dose ascending arm, results indicated that oral epetraborole AUC and C_{max} were similar in tablet and solution formulations, while time taken to reach C_{max}, or T_{max}, was slightly earlier for the solution formulation. The half-life for oral epetraborole was slightly lower on day one (approximately eight to 11 hours) compared to day 10 (approximately ten to 12 hours), though the 2,000 mg thrice-daily regimen showed a much longer half-life of approximately 100 hours. In general, oral epetraborole AUC and C_{max} exhibited low to moderate inter-subject variability. Data in the study indicated that steady state for oral epetraborole was generally achieved by day seven for all twice-daily regimens and by day four for thrice-daily regimens. Observed accumulation ranged from 55% to 84% for AUC and 19% to 43% for C_{max} with the largest accumulation observed in the thrice-daily regimen.

In the study, there were no SAEs and no dose-limiting treatment-emergent AEs at doses up to 4,000 mg/day. Doses up to 2,000 mg twice-daily (4,000 mg/day) were generally well-tolerated; dose-limiting gastrointestinal intolerability was observed when this dose was increased to 3,000 mg twice-daily (6,000 mg/day). The most common drug-related AEs observed were gastrointestinal in nature (nausea and vomiting).

Food effect (GSK LRS115244)—Phase 1 Study to Investigate Relative Bioavailability, Safety, and Tolerability Of Various Oral Formulations of Epetraborole

GSK previously initiated a Phase 1 study to evaluate the relative bioavailability of orally administered epetraborole (GSK2251052) in healthy volunteers, as epetraborole was initially being developed by GSK as an intravenous-to-oral switch regimen for cUTI. The study was originally planned as a five-part study; however, the first portion was only partially completed before the study was

terminated early based on emerging data from the Phase 2 cUTI trial described above. The study enrolled 24 participants to evaluate the relative bioavailability of five different oral formulations of 2,000 mg of epetraborole: enteric coated, modified release, powder for oral suspension, immediate release, and oral solution. Before the study was terminated, each subject received several of the five oral formulations of epetraborole.

In the study, no SAEs were observed.

Rationale for Use of Epetraborole in Treating NTM Lung Disease

We believe that the profile of epetraborole supports further development in patients with NTM lung disease while avoiding the development of clinical resistance for several reasons, including:

- Standard of care therapy for NTM lung disease is always a combination therapy with multiple antibiotics, thereby reducing the potential for the development of resistance;
- We have not observed any clinical resistance formation in the chronic model of NTM disease in mice;
- We have demonstrated in a HFS-MAC model the lack of resistance formation when dosed in combination for 21 days;
- Other frontline NTM and tuberculosis drugs have similar or higher frequencies of resistance formation and have been used successfully in clinical practice for decades;
- Epetraborole has been shown in a Phase 1 clinical trial in healthy volunteers to preferentially concentrate in alveolar macrophages, which are the cells infected with mycobacteria in NTM lung disease; and
- Epetraborole has demonstrated bactericidal activity in macrophages.

Based on the lack of dose-limiting treatment-emergent AEs at doses below 3,000 mg twice-daily (6,000 mg/day) in prior studies and trials, we do not anticipate any dose-limiting treatment-emergent adverse effects at our target doses.

EBO-101: Phase 1b Dose-Ranging Study

Previous clinical trials of epetraborole were limited to a maximum of 10-14 days of dosing. To support clinical development in NTM lung disease, we have completed a double-blind, placebo-controlled, Phase 1b dose-ranging study in healthy adult volunteers in Australia to assess the pharmacokinetics and safety of oral 28-day dosing of epetraborole (EBO-101). Dose Cohorts 1 through 5 were completed through the 28-day dosing period. One subject in Cohort 2 was replaced during the study due to an early withdrawal of consent. Cohort 6 was terminated early after a rise in COVID-19 cases in Australia resulted in recruitment difficulties and six of eight planned subjects were not enrolled. In addition, pharmacokinetic data from Cohort 6 was not necessary for selecting the expected epetraborole dose for our planned Phase 2/3 pivotal clinical trial, as adequate epetraborole exposures necessary for pharmacokinetic and pharmacodynamic target attainment for efficacy were obtained from lower doses in Cohorts 1 through 5 (ranging from 250 mg q24h to 1,000 mg q48h). The drug exposure data from Cohorts 1 through 4 was used to update the population pharmacokinetic model to determine the epetraborole dosage in our planned Phase 2/3 pivotal clinical trial (EBO-301). Based on the pharmacokinetic and pharmacodynamic targets derived from in vivo studies in preclinical mouse models of NTM lung disease and the high drug concentrations observed in a previous Phase 1 clinical trial conducted by GSK in lung macrophages, we intend to treat patients with NTM lung disease with an oral drug dose of 500 mg once daily. This dosage is substantially lower than those previously explored in the clinic for multidrug-resistant Enterobacterales, but we believe provides a high probability of reaching the target attainment to treat MAC lung disease along with a low number of drug-related adverse events. Our Phase 1b dose-ranging and food effect study is a randomized, placebo-controlled study being conducted in Adelaide, Australia in up to 51 healthy volunteers (39 randomized to epetraborole and 12 to placebo). 43 patients were enrolled in Cohorts 1 through 6 as of December 31, 2021. We received interim results from this study in the fourth quarter of 2021, and the

data analysis is ongoing. There were no serious treatment-emergent adverse events (TEAEs), severe TEAEs, or deaths in the study, and there were no withdrawals from the study due to TEAEs; 2 subjects withdrew from the study for personal reasons. Epetraborole plasma pharmacokinetic results were linear and predictable across all doses. Enrollment has begun in the final, open label, food-effect cohort (8 subjects) and remains to be completed. We believe the safety and pharmacokinetic results support further clinical development of epetraborole in NTM lung disease. The results were used in combination with preclinical data to determine epetraborole dosage for future NTM lung disease studies (500 mg once-daily).

Dose Cohort	Epetraborole Dose (mg)	Active: Placebo	Dosing Frequency (28 Days)
1	250 mg	6:2	q24h
2	500 mg	6:3†	q48h
3	500 mg	6:2	q24h
4	750 mg	6:2	q24h
5	1,000 mg	6:2	q48h
6	1,000 mg	6:2*	q24h
7	Food effect	8:0	Single dose

† Total enrollment for this cohort was 9 subjects. One placebo subject withdrew from the study for social reasons and was replaced by an alternate subject.

* Actual total enrollment is two subjects, not eight. Cohort 6 was terminated early after six of eight planned subjects were not enrolled due to a rise in COVID-19 cases in Australia that resulted in recruitment difficulties. In addition, pharmacokinetic data from Cohort 6 was not necessary for selecting the expected epetraborole dose for our planned Phase 2/3 pivotal clinical trial, as adequate epetraborole exposures necessary for efficacy were obtained from lower doses in Cohorts 1 through 5 (ranging from 250 mg q24h to 1,000 mg q48h).

Table 4. Dosing in the 28-day Phase 1b dose-ranging study of epetraborole

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

We have designed a Phase 2/3 pivotal clinical trial (EBO-301) that, based on our three interactions to date with the FDA, including discussions regarding our nonclinical microbiology, toxicology, and pharmacology data package for epetraborole and interim data from our Phase 1b dose-ranging study, we believe has the potential to be sufficient for regulatory approval in the United States. We plan to enroll patients with treatment-refractory MAC lung disease in this double-blind, placebo-controlled superiority trial, with planned enrollment of approximately 260 patients across approximately 80 clinical sites in up to 6 countries in North America and Europe. We expect that the primary objective in the Phase 3 part of this trial will be to determine if epetraborole plus an OBR, consisting of two or more standard-of-care drugs, is superior to placebo plus an OBR. An overview of the clinical trial design is below in Figure 9. We are working with the FDA to finalize the primary endpoint for our planned clinical trial, for which the FDA recommends a clinical response measure. We expect that the secondary endpoints will include other microbiological, clinical, and safety measures. We anticipate dosing of patients who culture convert to continue for an additional twelve months from the first month of culture clearance (three consecutive months of sputum clearance) in accordance to current treatment guidelines in a placebo-controlled blinded extension period of the trial. We recently received clearance of our IND application by the FDA, and plan to initiate patient enrollment in our Phase 2/3 clinical trial in the first half of 2022 with topline results for the Phase 2 part of the trial anticipated in the middle of 2023 and the Phase 3 part of the trial anticipated in the middle of 2024.

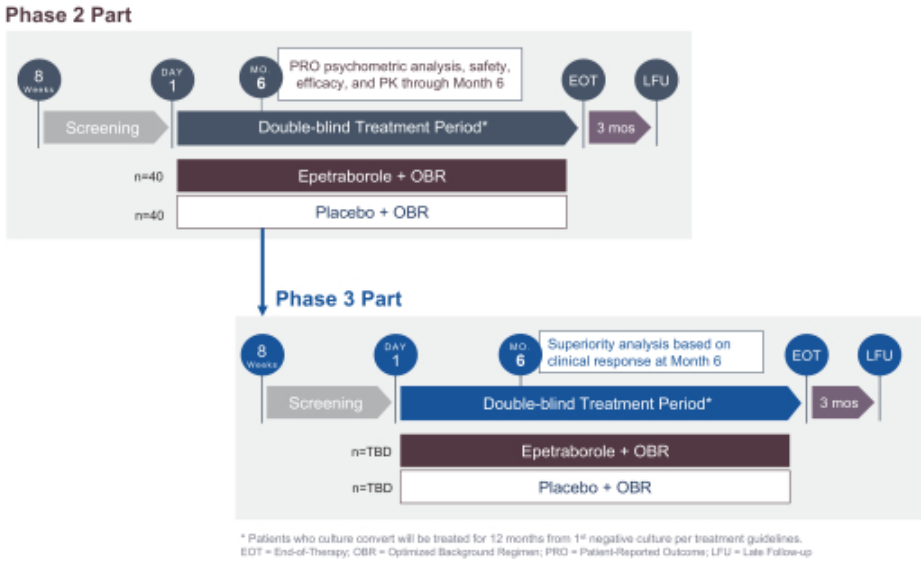


Figure 9. Proposed design of the Phase 2/3 pivotal clinical trial of epetraborole in treatment-refractory MAC lung disease

EBO-102: Planned Phase 1 Renal Impairment Study

Due to the prevalence of renal impairment among patients with NTM lung disease, we expect to initiate a Phase 1 study of epetraborole in subjects with renal impairment (EBO-102) prior to the initiation of our planned Phase 2/3 pivotal clinical trial (EBO-301). The objective of the EBO-102 Phase 1 renal impairment study will be to assess safety and pharmacokinetics of oral epetraborole in subjects with varying degrees of renal function (normal to severe). We recently received clearance of our IND application by the FDA, and plan to initiate patient enrollment in this renal impairment trial in the first half of 2022 with topline results anticipated in the second half of 2022, which we do not expect will delay the start of our planned Phase 2/3 pivotal clinical trial in patients with NTM lung disease.

Future Development of Epetraborole

We intend to conduct clinical trials in Japan in patients with treatment-refractory MAC lung disease. Japan has some of the highest rates of NTM lung disease in the world. It is believed that these high rates are related to a combination of environmental factors, such as soil and humidity and other climate conditions, behavioral differences, and an aging population. We estimate that there are 220,000 patients with NTM lung disease and 21,000 patients with treatment-refractory MAC lung disease in Japan. We have initiated discussions with the PMDA to gain alignment on the development plan necessary for regulatory approval of epetraborole in MAC lung disease. Our initial planned indication in all geographies is the treatment of patients with treatment-refractory MAC lung disease.

We also intend to conduct trials in which we plan to incorporate epetraborole as part of first line combination treatment of treatment-naive patients with NTM lung disease, which we believe is supportable with data from our Phase 1b study. We believe that the addition of epetraborole to first line treatment has the potential to significantly improve response rates without increasing adverse events.

Additionally, we intend to pursue development of epetraborole as a first line therapy in *M. abscessus* lung disease. Many of the current treatments lead to poor efficacy (~50%), are delivered by intravenous infusion, have significant side effects, and lead to the development of multi-drug

resistance. We believe that epetraborole, in combination with other drugs, has the potential to treat *M. abscessus* based on its in vitro and in vivo potency against multiple isolates.

Expansion of Our Portfolio of Product Candidates

We have deep expertise in boron chemistry as exemplified by our management 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 in 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 toughest 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. Our highest priority is melioidosis. We are currently conducting preclinical research with the Mahidol Oxford Tropical Medicine Research Unit, or MORU, in Thailand, Colorado State University, and the NIH in the United States for melioidosis. We believe these partners provide substantial technical and capital resources to advance the melioidosis programs and provide material benefits to our company and to our NTM program.

Melioidosis is an infectious disease caused by the bacterium *B. pseudomallei*. It is endemic to tropical regions of the world with the majority of cases occurring in South Asia. It is contracted from direct contact with contaminated soil and water and is not transmitted person-to-person. Similar to NTM, *B. pseudomallei* is an intra-cellular pathogen in macrophages. Infections 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. Beginning in 2011 and 2020, respectively, in vitro studies have been conducted by the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) (N=30 isolates) and MORU (N=277 isolates) with MIC_{90} values of 2 µg/mL and 4 µg/mL, including isolates that are resistant to the standard of care drug, ceftazidime. Studies conducted at Colorado State University (Slayden Lab) in 2021 showed that the addition of epetraborole to ceftazidime improves in vivo bacterial killing over ceftazidime alone. Currently we are conducting in vitro hollow-fiber experiments of epetraborole and ceftazidime in combination against *B. pseudomallei*, which are funded by the NIH and conducted by Praedicare Inc.

Adjuvant Global Health Agreement

We have entered into an Amended and Restated Global Health Agreement, or the Global Health Agreement, with Adjuvant Global Health Technology Fund L.P. and Adjuvant Global Health Technology Fund DE L.P., or together, Adjuvant, in connection with Adjuvant's investment of $12.0 million in our Series A and Series B redeemable convertible preferred stock financings. 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 lower-middle income target countries. The purpose of Adjuvant's investment is to support the development of epetraborole for infectious diseases, including 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. For instance, we may sell epetraborole for melioidosis, tuberculosis and any other mutually agreed-upon products in the target countries at a maximum price of 25% above the cost of sales and we must provide a sufficient volume to meet the demands of non-profit organizations and public-sector purchasers. We are not required to sell any products at a loss. In addition, we are required to develop regulatory strategies and pursue necessary product registrations, as well as actively seek funding from governmental grants and other granting sources, to advance the development of epetraborole for melioidosis, tuberculosis, and any other mutually agreed-upon products. If we do not maintain compliance with these and other program-related investment 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. 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 meliodosis, tuberculosis, and any other mutually agreed-upon products.

In the event of the assignment, sale, exclusive license, or other transfer of intellectual property related to epetraborole for melioidosis, tuberculosis, or any other mutually agreed-upon products, we must ensure that the program-related investment global access commitments are expressly assumed by the purchaser, transferee, licensee, or acquirer. Upon the occurrence of certain events, including the failure, by ourselves or any successor to prosecute material intellectual property that is subject to program-related investment commitments, 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. Such a license grant will be subject to the licensing terms associated with the Anacor license agreement.

In the event that we fail to operate in accordance with the program-related investment commitments under the Global Health Agreement or fail to comply with the provisions of the Global Health Agreement, we are required to notify Adjuvant in writing within 30 days of the event causing such non-compliance and must describe the steps we will take to rectify the situation within 30 days following the notice. If Adjuvant believes we have failed to operate in accordance with the program-related investment commitments under the Global Health Agreement or have failed to comply with the provisions of the Global Health Agreement, Adjuvant is required to notify us and specify the basis for their determination and request that we rectify the situation within 30 days following their notice.

These global access commitments became effective in 2019 at the closing of the Series A redeemable convertible preferred stock financing and will remain in effect until the latter of (i) the date that Adjuvant ceases to be a shareholder of our company or (ii) ten years following approval of epetraborole for melioidosis, tuberculosis, and any other mutually agreed-upon products by a stringent regulatory authority, such as the FDA or EMA.

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) for epetraborole.

In connection with the execution of the Anacor Agreement, we paid to Anacor a non-refundable upfront payment of $2.0 million and granted Anacor 579,064 shares of Series A redeemable convertible preferred stock. Additionally, we agreed to make further payments to Anacor upon achievement of various development milestones for an aggregate maximum payment of $2.0 million, various commercial and sales threshold milestones for an aggregate maximum payment of $125.0 million, and up to 50% of royalties received under certain sublicensing arrangements. Royalties are subject to certain customary reductions, including lack of patent coverage and generic product entry. We also agreed to pay Anacor non-refundable, non-creditable sales royalties on a tiered marginal royalty rate based on the country's status as a developing or developed country as defined in the license agreement. Sales royalties are a percentage of net sales, as specified in the Anacor Agreement, and range from mid-single digit percentages for developing countries and single to mid-teen percentages for developed countries or the China, Hong Kong, Taiwan, and Macau territories. The sales royalties are required to be paid on a product-by-product and country-by-country basis, until the latest to occur of (i) 15 years following from the date of first commercial sale of a product in such country, (ii) the expiration of all regulatory or data exclusivity for such product in such country, or (iii) the date of the expiration of the last to expire valid claim of a licensed patent covering such product in such country. Currently, the date of the expiration of the last to expire valid claim of a
licensed patent covering epetraborole in the licensed territory is June 2028. In addition, Anacor is entitled to certain milestone payments upon a change of control of our company.

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

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

License Agreement with Brii Biosciences Limited

In November 2019, we entered into a license agreement, or the Brii Biosciences License Agreement, pursuant to which we granted Brii Biosciences an exclusive, perpetual, sublicensable

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

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

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

Global Health Agreement with Adjuvant Global Health Technology Fund

We entered into the Global Health Agreement with Adjuvant in connection with Adjuvant's investment 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 1,033,057 shares of our redeemable convertible preferred stock. 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. For a more detailed description of the Global Health Agreement with Adjuvant, please see the section titled "—Our Global Health Initiatives—Adjuvant Global Health Agreement."

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, 2021, 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 “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 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 United States Patent and Trademark Office reviews and approves the application for any Patent Term Extension in consultation with the FDA.

As of December 31, 2021, we exclusively licensed three U.S. patents, 38 foreign patents, and approximately six pending foreign patent applications, covering our key programs and pipeline. We do not own any issued patents. We own two pending U.S. provisional patent applications, which are not eligible to become issued patents until, among other things, we file a non-provisional U.S. patent application within one year of filing of the U.S. provisional patent application with the USPTO.

Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office 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, Moldovia, 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 “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 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 indications 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, 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, and before an NDA is submitted. Meetings at other times may be 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.

Any 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 and accelerated approval. 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 receive accelerated approval 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, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for 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 indication 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 many 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 U.S., by way of example, in March 2010, the 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.

Regulation and Procedures Governing Approval of Medicinal Products in the EU

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to sell any of our product candidates outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by equivalent competent authorities in foreign jurisdictions before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

The process governing the marketing authorization, or MA, of medicinal products in the EU entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety, quality, and efficacy of the medicinal product for each proposed therapeutic indication.

It also requires the submission to the relevant competent authorities of a marketing authorization application, or MAA and granting of an MA by these authorities before the product can be marketed and sold in the EU.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states, as well as Norway, Liechtenstein, and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, or with other applicable regulatory requirements may result in administrative, civil, or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal, or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties.

Non-Clinical Studies and Clinical Trials

Similar to the United States, the various phases of non-clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU member states govern the system for the approval of clinical trials in the EU.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on International Conference on Harmonization, or ICH, guidelines on GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

Under the applicable regulatory system, an applicant must obtain prior approval from the competent national authority of the EU member states in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a related favorable opinion. The application for authorization of a clinical trial must be accompanied by, among other documents, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation as prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the related implementing national provisions of the individual EU member states, and further detailed in applicable guidance documents. Any substantial changes to the trial protocol or to other information submitted with the clinical trial application must be notified to or approved by the relevant competent national authorities and ethics committees. Medicinal products used in clinical trials must be manufactured in accordance with GMP.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014, or Clinical Trials Regulation, was adopted. The Regulation is anticipated to enter into force on January 31, 2022. The Clinical Trials Regulation will be directly applicable in all of the EU member states, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound

by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which on-going clinical trials will be governed by the Clinical Trials Regulation will depend on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application, as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted (member states concerned). Part II is assessed separately by each member state concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines will be defined by the Clinical Trials Regulation.

Marketing Authorizations

To obtain an MA for a product in the EU, an applicant must submit an MAA either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the EU member states (decentralized procedure, national procedure, or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EU member states. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune, and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP, is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (not including clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU member state in which the product is to be marketed. This application is identical to the application that

would be submitted to the EMA for authorization through the centralized procedure. The reference EU member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU member states who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU member state cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures—Human (CMDh) for review. The subsequent decision of the European Commission is binding on all EU member states.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU member state to apply for this authorization to be recognized by the competent authorities in other EU member states. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU member states of the MA of a medicinal product by the competent authorities of other EU member states. The holder of a national MA may submit an application to the competent authority of an EU member state requesting that this authority recognize the MA delivered by the competent authority of another EU member state.

In principle, an MA has an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU member state in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document (eCTD) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU member states may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in case of centralized procedure) or on the market of the authorizing EU member state within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. It permits increased interaction and early dialogue with companies developing promising medicinal products, to optimize their product development plans and speed up their evaluation to help the product reach patients earlier than normal. Product developers that benefit from PRIME designation are potentially eligible for accelerated assessment of their MAA although this is not guaranteed. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA will cease to be renewed.

An MA may also be granted “under exceptional circumstances” where the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization, and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU GMP standards when manufacturing medicinal products and APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU member states. MA holders, manufacturing and import authorization (MIA) holders, or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU member states’ requirements applicable to the manufacturing of medicinal products.

Data and Market Exclusivity

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and ten years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator’s data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator’s data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU’s regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU member states and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Orphan Medicinal Products

Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000, provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in ten thousand persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

In the EU, an application for designation as an orphan product can be made any time prior to the filing of the MAA. Orphan medicinal product designation entitles an applicant to incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized MA procedure. Upon grant of an MA, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another MAA, or grant an MA, or accept an application to extend an MA for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any SPC can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the ten year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-Approval Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion, and sale of medicinal products.

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission, or the competent regulatory authorities of the individual EU member states. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member states' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

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 December 31, 2021, we had 23 full-time employees, consisting of clinical, research, development, manufacturing, regulatory, finance, and operational personnel. Ten of our employees hold Ph.D. or M.D. degrees. 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.

Facilities

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 2022. 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 2022.

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.

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. 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. 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.

Legal Proceedings

From time to time, we may become involved in material legal proceedings or be subject to claims arising in the ordinary course of our business. We are currently not party to any legal proceedings material to our operations or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by a government authority.

Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources, and other factors, and there can be no assurances that favorable outcomes will be obtained.

MANAGEMENT

Executive Officers, Management, and Directors

The following table sets forth information regarding our executive officers and directors as of October 31, 2021.

Name	Age	Position
Executive Officers:		
Eric Easom	54	Chief Executive Officer and Director
Lucy Day	62	Chief Financial Officer
Sanjay Chanda, Ph.D.	57	Chief Development Officer
Paul Eckburg, M.D.	51	Chief Medical Officer
Kevin Krause	47	Chief Strategy Officer
Non-Employee Directors:		
Joseph Zakrzewski	58	Chair and Director
Kabeer Aziz	32	Director
Gilbert Lynn Marks, M.D.	64	Director
Patricia Martin	61	Director
Rob Readnour, Ph.D.	57	Director
Stephanie Wong	48	Director

Executive Officers

Eric Easom has served as our President and Chief Executive Officer and a member of our board of directors 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 Masters 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 of directors.

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 CFO, Vice President of Finance, and Vice President, Human Resources and Finance at Anacor. From February 1994 to January 2002, Ms. Day served in various financial roles at Centaur Pharmaceuticals, Inc. a biopharmaceutical company, including as chief financial officer. Ms. Day has previous experience at 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.

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, a pharmaceutical

company. From October 2016 to August 2017, he served as the Chief Development Officer of Tioma Therapeutics, 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/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. Since August 2019, Dr. Eckburg served as an interim Chief Medical Officer and subsequent expert scientific advisor at SNIPR Biome, a CRISPR microbiome company. Since June 2016, he served as an interim Chief Medical Officer and subsequent scientific advisory board member at Bugworks Research Inc., a biopharmaceutical company. Since July 2016, he has served as a consultant at Spero Therapeutics, a biopharmaceutical company. Since February 2015, Dr. Eckburg has served as a consultant and Safety Monitoring Board member at Paratek Pharmaceuticals, a biopharmaceutical company. Since February 2015, he has served as a scientific advisory board member for Cūrza, a biopharmaceutical company. From February 2018 to May 2019, he served as acting Chief Medical Officer at UTILITY therapeutics, a biotechnology company. From April 2017 to May 2019, Dr. Eckburg served as the acting Vice President of Clinical Development at Recida Therapeutics, a biopharmaceutical company. From April 2016 to May 2019, he served as the acting Chief Medical Officer at Geom Therapeutics, 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, 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, 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 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, including the position 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. 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.

Non-Employee Directors

Joseph Zakrzewski has served as a member of our board of directors since May 2017. Mr. Zakrzewski currently serves as the Chairman of the board of directors of Cerecin, a biopharmaceutical company and Cyteir Therapeutics, a publicly traded biotechnology company. Mr. Zakrzewski also currently serves as a member of the board of directors of Sangamo Therapeutics, Inc., a publicly traded biotechnology company, Acceleron Pharma, a publicly traded biotechnology company, and Amarin Corporation, a publicly traded biopharmaceutical company. From 2014 to 2020, Mr. Zakrzewski served as a

member of the board of directors of Site One Therapeutics, a pharmaceutical company. From December 2009 to December 2013, Mr. Zakrzewski also served as the Chairman and Chief Executive Officer of Amarin Corporation, a publicly traded biopharmaceutical company. 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 of directors.

Kabeer Aziz has served as a member of our board of directors 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, Pulmocide, Quantoom Biosciences and Frontier Nutrition and is a board observer to YishengBio. 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 of directors.

Gilbert Lynn Marks, M.D., has served as a member of our board of directors since February 2020. From September 2017 to September 2021, Dr. Marks was employed by Tunnell Government Services, or TGS, and became a Vice President in January 2020 at TGS, a subsidiary of Tunnell Consulting, Inc. that supports clients in medical product development. As an employee of TGS, he served as a contractor supporting the Office of the Director for the Biomedical Advanced Research and Development Authority, or BARDA, a U.S. Department of Health and Human Services office responsible for the procurement and development of medical countermeasures for chemical, biological radiological, nuclear, and pandemic threats, including COVID-19. From 2016 to 2021, Dr. Marks served as a member of the Advisory Committee for the National Center for Advancing Translational Sciences, or NCATS, an institute at the National Institutes of Health. As part of his support for NCATS, he also served as Chair of the Cures Acceleration Network Review Board. From 2006 to 2018, Dr. Marks served on the Scientific Advisory Board for the TB Alliance, a not-for-profit organization, including serving as Chair. Since 2020, he has served on the Scientific Review Board for the Medicines for Malaria Venture, a not-for-profit organization and has agreed to Chair the Committee starting in 2022. Since 2009, he has served on the Scientific Advisory Committee for the Polio Antiviral Initiative. Since 2017, Dr. Marks has served as a member of the Board of Directors for WOAR, Philadelphia, Pennsylvania's not for profit rape crisis support center. From 1993 to 2017, Dr. Marks served in multiple roles at GlaxoSmithKline plc, a publicly traded pharmaceutical company, including serving as Senior Vice President in Research & Development and as a member of the Pharmaceuticals R&D Leadership team. He also served as Senior Clinical Advisor for 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. He is Board Certified in Internal Medicine and Infectious Diseases. 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 of directors.

Patricia (Patty) Martin has served as a member of our board of directors since April 2021. Since July 2019, Ms. Martin has served as the President and Chief Executive Office of BioCrossroads, a company 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, 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, 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 & 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 of directors.

Rob Readnour, Ph.D., has served as a member of our board of directors 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, a publicly traded pharmaceutical company that was previously part of Eli Lilly & Co, 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, a bio-systems company focused on animal health, Advanced Animal Diagnostics, an animal health device company, Skyline Vet Pharma, a veterinary pharmaceutical company, Exubrion Therapeutics, a radiotherapeutic veterinary device company, Appello Pharmaceuticals, a drug development company, and NuSirt, a drug and nutraceutical compound development company. Dr. Readnour also currently serves as the Executive Chairman of In the Bowl Animal Health, an animal health company. Dr. Readnour is also the Chief Executive Officer of Borah, 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 of directors.

Stephanie Wong has served as a member of our board of directors since April 2021. Ms. Wong has served as the Chief Financial Officer at Calithera Biosciences, 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, a publicly traded pharmaceutical company, most recently as Vice President, Finance and Controller. Prior to that, Ms. Wong served in senior finance roles at AcelRx Pharmaceuticals and Kosan Biosciences, and as an audit manager at PricewaterhouseCoopers. 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 of directors.

Composition of Our Board of Directors

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling, and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Certain members of our board of directors were elected under the provisions of our Amended and Restated Voting Agreement entered into in March 2021, or the Voting Agreement, which will terminate upon the closing of this offering. Under the terms of our Voting Agreement, the stockholders who are party to the Voting Agreement have agreed to vote their respective shares to elect: (i) one director designated by MGC Venture Partners 2018 LP, currently Rob Readnour; (ii) one director designated by

Adjuvant Global Health Technology Fund L.P., currently Kabeer Aziz; (iii) one director who shall be our then-current Chief Executive Officer, currently Eric Easom; (iv) one director elected by the holders of a majority of the shares of our common stock, currently Joseph Zakrzewski; and (v) three directors who are not our employees or affiliates, with such individuals to be designated by mutual agreement of our board of directors, currently Gilbert Marks, Patricia Martin, and Stephanie Wong. The Voting Agreement will terminate upon the closing of this offering, and upon the closing of the offering no stockholder will have any special rights regarding the election or designation of the members of our board of directors. Our current directors elected to our board of directors pursuant to the Voting Agreement will continue to serve as directors until their successors are duly elected and qualified by holders of our common stock.

Our board of directors may establish the authorized number of directors from time to time by resolution. In accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be , and , and their terms will expire at the annual meeting of stockholders to be held in 2023;
- the Class II directors will be and , and their terms will expire at the annual meeting of stockholders to be held in 2024; and
- the Class III directors will be and , and their terms will expire at the annual meeting of stockholders to be held in 2025.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Under the Nasdaq Listing Rules independent directors must comprise a majority of our board of directors as a listed company within one year of the listing date.

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment and affiliations, including family relationships, our board of directors has determined that none of our directors, other than Mr. Easom, has any 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 Nasdaq Listing Rules. Our board of directors 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 of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled “Certain Relationships and Related Person Transactions.”

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee intends to adopt a written charter that satisfies the application rules and regulation of the SEC and the Nasdaq Listing Rules, which we will post to our website at www.an2therapeutics.com upon the closing of this offering. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Our audit committee currently consists of Stephanie Wong, Kabeer Aziz, and Rob Readnour, each of whom our board of directors has determined satisfies the independence requirements under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is Stephanie Wong, who our board of directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. 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 of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial-statement audits, and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence, and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Compensation Committee

Our compensation committee currently consists of Patricia Martin, Joseph Zakrzewski, and Gilbert Marks. The chair of our compensation committee is Patricia Martin. Our board of directors has determined that each member of our compensation committee is independent under the Nasdaq Listing Rules and as a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs, and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- reviewing and approving the compensation of our chief executive officer, other executive officers, and senior management;
- reviewing and recommending to our board of directors the compensation paid to our directors;
- reviewing and approving the compensation arrangements with our executive officers and other senior management;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending, and terminating, incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections, and any other compensatory arrangements for our executive officers and other senior management;
- reviewing, evaluating, and recommending to our board of directors succession plans for our executive officers; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation strategy, including base salary, incentive compensation, and equity-based grants, to assure that it promotes stockholder interests and supports our strategic and tactical objectives, and that it provides for appropriate rewards and incentives for our management and employees.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of , and . The chair of our nominating and corporate governance committee is . Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq Listing Rules, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors and orientation of new directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors and management.

Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt a written Code of Business Conduct and Ethics that applies to all our employees, officers, and directors. This includes our principal executive officer, principal financial officer, and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics will be posted on our website at www.an2therapeutics.com. We intend to disclose on our website any future amendments of our Code

of Business Conduct and Ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions, or our directors from provisions in the Code of Business Conduct and Ethics. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last calendar year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Non-Employee Director Compensation

During the year ended December 31, 2020, each of the following individuals served on our board of directors as non-employee directors: Kabeer Aziz, Gilbert Marks, Rob Readnour, and Joseph Zakrzewski.

The following table presents all of the compensation awarded to or earned by or paid to our named non-employee directors during the fiscal year ended December 31, 2020.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Gilbert Marks, M.D.(2)	25,000	6,940	31,940

(1) All of the option awards were granted under the 2017 Plan, the terms of which plan are described below under “Executive Compensation—Equity Benefit Plans—2017 Equity Incentive Plan.” The amounts shown represent the grant date fair values of option awards granted in 2020 as computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Topic 718. See Note 2 to our financial statements included elsewhere in this prospectus for a discussion of the assumption used in the calculation.

(2) During the year ended December 31, 2020, Dr. Marks was granted 9,703 options to purchase common stock. These options vest over 48 months, subject to Dr. Marks’ continued service with us through each vesting date. All options are exercisable. As of December 31, 2020, 9,703 options were not vested.

Messrs. Aziz and Zakrzewski and Dr. Readnour also served on our board of directors during the year ended December 31, 2020 but did not receive any compensation for their service as directors. Mr. Easom also served on our board of directors during the year ended December 31, 2020 but did not receive any additional compensation for his service as a director. See the section titled “Executive Compensation” for more information regarding the compensation earned by Mr. Easom.

We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

We intend to adopt a non-employee director compensation policy, pursuant to which our non-employee directors will be eligible to receive compensation for service on our board of directors and committees of our board of directors, to be effective following the completion of this offering.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2020 were:

- Eric Easom, our Chief Executive Officer;
- Lucy Day, our Chief Financial Officer; and
- Sanjay Chanda, our Chief Development Officer.

Summary Compensation Table

The following table presents all of the compensation awarded to or earned by or paid to our named executive officers during the fiscal year ended December 31, 2020.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)	Total ($)
Eric Easom *President and Chief Executive Officer*	2020	340,000	–	122,400	–	462,400
Lucy Day(3) *Chief Financial Officer*	2020	83,917	19,558	50,000	–	153,475
Sanjay Chanda, Ph.D. *Chief Development Officer*	2020	310,000	28,022	83,700	–	421,722

(1) Amounts reflect the full grant-date fair value of stock options granted during 2020 computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Topic 718, rather than the amounts paid to or realized by the named individual. See Note 2 to our financial statements included elsewhere in this prospectus for a discussion of the assumption used in the calculation. All of the option awards were granted under the 2017 Plan, the terms of which plan are described below under “Executive Compensation—Equity Benefit Plans—2017 Equity Incentive Plan.”

(2) Amounts represent the annual performance-based cash bonuses earned by our named executive officers based on the achievement of certain corporate performance objectives during 2020. The target bonus amounts for Mr. Easom, Ms. Day, and Dr. Chanda were $136,000, $54,000, and $93,000, respectively. In December of 2020, our board of directors assessed company performance against our 2020 corporate goals and based on such performance, awarded a cash annual incentive bonus to each of our named executive officers equal to 90% of his or her target bonus amount for 2020. Ms. Day was additionally awarded a discretionary bonus of $34,895. These amounts were paid to the named executive officers in early 2021.

(3) Ms. Day commenced part-time employment with us in 2019 on a 25% basis. She commenced full-time employment with us on December 1, 2020.

Outstanding Equity Awards as of December 31, 2020

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2020.

	Option Awards[1]					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price Per Share ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Eric Easom	2/24/2017[2]	–	–	–	–	–	–
Lucy Day	1/23/2020[3]	6,153	9,393	0.99	1/22/2030	–	–
	10/5/2020[4]	156	3,600	0.99	9/23/2030	–	–
	12/9/2020[5]	–	9,600	0.99	1/22/2030	–	–
Sanjay Chanda, Ph.D.	1/23/2020[6]	13,537	20,664	0.99	1/22/2030	–	–
	10/5/2020[7]	344	7,920	0.99	9/23/2030	–	–

(1) All of the option awards were granted under the 2017 Plan, the terms of which plan are described below under “Executive Compensation—Equity Benefit Plans—2017 Equity Incentive Plan.”

(2) Mr. Easom acquired 550,000 shares of our common stock pursuant to a common stock purchase agreement. As of December 31, 2020, all shares were vested.

(3) 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 Ms. Day’s continued service with us through each vesting date. As of December 31, 2020, 6,153 shares were vested and 9,393 shares were not vested. The option is subject to the vesting acceleration provision described below under “—Potential Payments upon Termination or Change in Control.”

(4) The option vests in respect of 1/48th of the underlying shares shall vest on each monthly anniversary of the vesting commencement date, subject to Ms. Day’s continued service with us through each vesting date. All options are exercisable. As of December 31, 2020, 156 shares were vested and 3,600 shares were not vested. The option is subject to the vesting acceleration provision described below under “—Potential Payments upon Termination or Change in Control.”

(5) The option vests in respect of 1/48th of the underlying shares shall vest on each monthly anniversary of the vesting commencement date, subject to Ms. Day’s continued service with us through each vesting date. As of December 31, 2020, 9,600 shares were not vested. The option is subject to the vesting acceleration provision described below under “—Potential Payments upon Termination or Change in Control.”

(6) 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. Chanda’s continued service with us through each vesting date. As of December 31, 2020, 13,537 shares were vested and 20,664 shares were not vested. The option is subject to the vesting acceleration provision described below under “—Potential Payments upon Termination or Change in Control.”

(7) The option vests in respect of 1/48th of the underlying shares shall vest on each monthly anniversary of the vesting commencement date, subject to Dr. Chanda’s continued service with us through each vesting date. As of December 31, 2020, 344 shares were vested and 7,920 shares were not vested. The option is subject to the vesting acceleration provision described below under “—Potential Payments upon Termination or Change in Control.”

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Pension Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the fiscal year ended December 31, 2020.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during the fiscal year ended December 31, 2020.

Offer Letters

Below are descriptions of our offer letters with our named executive officers. The offer letters with our executive officers generally provide for at-will employment and set forth the executive officer's initial base salary, annual target bonus, and eligibility to participate in our employee benefit plans.

Eric Easom

On November 19, 2019, Eric Easom entered into an employment agreement with us to serve as our President and Chief Executive Officer on an at-will basis. Pursuant to Mr. Easom's employment agreement, Mr. Easom's initial base salary was $340,000. Currently, his annual base salary is $390,000, and he is eligible for an annual target bonus of 40% of his base salary.

Mr. Easom is entitled to certain equity acceleration benefits in the event of an employment termination in certain circumstances, which are described below under "—Potential Payments upon Termination or Change in Control."

Lucy Day

On November 19, 2019, Lucy Day entered into an employment agreement with us to serve as our Chief Financial Officer on an at-will basis. Pursuant to Ms. Day's employment agreement, Ms. Day's initial base salary was $67,000 for her services working on a 25% basis, increasing up to 100% as the Company's requirements for her services increased. Currently, her annual base salary is $311,800, and she is eligible for an annual target bonus of 30% of her base salary. In connection with her employment, Ms. Day was granted an initial first option award to purchase 15,546 shares of our 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, a second option award to purchase 3,756 shares of our common stock, 1/48th of which vest on a monthly basis, and a third option award to purchase 9,600 shares of our common stock, 1/48th of which vest on a monthly basis.

Ms. Day is entitled to certain equity acceleration benefits in the event of an employment termination in certain circumstances, which are described below under "—Potential Payments upon Termination or Change in Control."

Sanjay Chanda

On November 19, 2019, Sanjay Chanda entered into an employment agreement with us to serve as our Chief Development Officer on an at-will basis. Pursuant to Dr. Chanda's employment agreement,

Dr. Chanda's initial base salary was $310,000. Currently, his annual base salary is $360,000, and he is eligible for an annual target bonus of 30% of his base salary. In connection with his employment, Dr. Chanda was granted an initial first option award to purchase 34,201 shares of our 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, and a second option award to purchase 8,264 shares of our common stock, 1/48th of which vest on a monthly basis.

Dr. Chanda is entitled to certain equity acceleration benefits in the event of an employment termination in certain circumstances, which are described below under "—Potential Payments upon Termination or Change in Control."

Potential Payments and Benefits upon Termination or Change in Control

Each of our named executive officers entered into a Change in Control Agreement with us on June 23, 2020, each of which provides that, if the executive is terminated by us without "cause" (other than as a result of death or disability), or if the executive resigns for "good reason," in each case, in connection with or within 12 months following a "change in control," then, subject to the executive's execution of a release of claims, 100% of his or her unvested stock awards will immediately vest and become exercisable, and, to the extent applicable, our right of repurchase or reacquisition with respect to such stock awards will lapse.

"Cause" has the same meaning as such term in any effective employment agreement, or, in the event that an employment agreement does not provide for such definition, any one of the following events: (i) the commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) the attempted commission of, or participation in, a fraud or act of dishonesty against us; (iii) the intentional, material violation of any contract or agreement between the executive and us or of any statutory duty owed to us; (iv) unauthorized use or disclosure of our confidential information or trade secrets; or (v) gross misconduct.

"Good reason" means the occurrence of any of the following without the executive's written consent: (i) a material reduction in job duties or responsibilities inconsistent with the executive's position with the Company; provided, however, that any such reduction or change after a "change in control" will not constitute "good reason" if executive retains reasonably comparable duties and responsibilities with respect to the company's business within the successor entity following a "change in control"; (ii) a material reduction of the executive's then-current base salary or target bonus; (iii) the relocation of executive's principal place of employment to a place that increases executive's one-way commute by more than 50 miles as compared to the executive's then-current principal place of employment immediately prior to such relocation; (iv) any material breach by the Company of the 2017 Plan or any other written agreement between the Company and the executive; or (v) the failure by any successor to the Company to assume the 2017 Plan and any obligations under the 2017 Plan. The executive must give written notice to the Company of the event forming the basis of the termination for "good reason" within 60 days after the date on which the Company gives written notice to the executive of the Company's affirmative decision to take an action set forth in clauses (i), (ii), (iii), (iv), or (v) above, the Company fails to cure such basis for "good reason" resignation within 30 days after receipt of the executive's written notice and the executive terminates his or her position with the Company within 30 days following the expiration of the cure period.

"Change in control" means the first to occur of any of the following transactions that also constitutes a change in the ownership or effective control of the Company, or a change in the ownership of a substantial portion of the Company's assets, as described in U.S. Treasury Regulation Section 1.409A-3(i)(5): (A) a merger or consolidation in which the Company is not the surviving entity,

except for a transaction the principal purpose of which is to change the state in which the Company is incorporated or any transaction that is a financing transaction (*i.e.*, one in which a majority of the members of the board of directors prior to such financing transaction constitute the majority of the members of the board of directors immediately after the closing of such financing transaction); (B) the sale, transfer, lease, or other disposition of all or substantially all of the assets of the Company (including the capital stock of the Company's subsidiary corporations); (C) any reverse merger in which the Company is the surviving entity but in which securities possessing more than 50% of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger; or (D) an acquisition in a single or series of related transactions by any person or related group of persons (other than the Company or by a Company-sponsored employee benefit plan) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than 50% of the total combined voting power of the Company's outstanding securities.

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

Our named executive officers are eligible to participate in our defined contribution retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may elect to defer a percentage of their eligible compensation into the plan on a pretax or after tax basis, up to annual limits prescribed by the Code.

Equity Benefit Plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants, and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain, and motivate employees, consultants, and directors, and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus forms a part.

2022 Equity Incentive Plan

In , our board of directors adopted, and our stockholders approved, our 2022 Plan. We expect our 2022 Plan will become effective on the date of the underwriting agreement related to this offering. Our 2022 Plan came into existence upon its adoption by our board of directors, but no grants will be made under our 2022 Plan prior to its effectiveness. Once our 2022 Plan becomes effective, no further grants will be made under our 2017 Plan.

Awards. Our 2022 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, and other forms of awards to our employees, directors, and consultants, and any of our affiliates' employees and consultants.

Authorized Shares. Initially, the maximum number of shares of our common stock that may be issued under our 2022 Plan after it becomes effective will not exceed shares of our common

stock, which is the sum of (i) new shares, plus (ii) an additional number of shares not to exceed shares, consisting of (a) shares that remain available for the issuance of awards under our 2017 Plan as of immediately prior to the time our 2022 Plan becomes effective and (b) any shares of our common stock subject to outstanding stock options or other stock awards granted under our 2017 Plan that, on or after our 2022 Plan becomes effective, terminate, or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares of our common stock reserved for issuance under our 2022 Plan will automatically increase on January 1 of each year for a period of ten years, beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to (1) % of the total number of shares of our common stock outstanding on December 31 of the immediately preceding year, or (2) a lesser number of shares determined by our board of directors no later than December 31 of the immediately preceding year. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2022 Plan is shares.

Shares subject to stock awards granted under our 2022 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares will not reduce the number of shares available for issuance under our 2022 Plan. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation will not reduce the number of shares available for issuance under our 2022 Plan. If any shares of our common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us (i) because of a failure to meet a contingency or condition required for the vesting of such shares; (ii) to satisfy the exercise, strike or purchase price of a stock award; or (iii) to satisfy a tax withholding obligation in connection with a stock award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under our 2022 Plan.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, administers our 2022 Plan. Our board of directors may delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards; and (ii) determine the number of shares subject to such stock awards. Under our 2022 Plan, our board of directors has the authority to determine stock award recipients, the types of stock awards to be granted, grant dates, the number of shares subject to each stock award, the fair market value of our common stock, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

Under our 2022 Plan, our board of directors also generally has the authority to effect, with the consent of any materially adversely affected participant, (i) the reduction of the exercise, purchase, or strike price of any outstanding option or stock appreciation right; (ii) the cancellation of any outstanding option or stock appreciation right and the grant in substitution therefore of other awards, cash, or other consideration; or (iii) any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the administrator. The administrator determines the exercise price for stock options, within the terms and conditions of our 2022 Plan, except the exercise price of a stock option generally will not be less than 100% of the fair market value of our common stock on the date of grant. Options granted under our 2022 Plan will vest at the rate specified in the stock option agreement as determined by the administrator.

The administrator determines the term of stock options granted under our 2022 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement, or other written agreement between us and the optionholder, provide otherwise, if an optionholder's service relationship

with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the administrator and may include (i) cash, check, bank draft, or money order; (ii) a broker-assisted cashless exercise; (iii) the tender of shares of our common stock previously owned by the optionholder; (iv) a net exercise of the option if it is an NSO; or (v) other legal consideration approved by the administrator.

Unless the administrator provides otherwise, options generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft, or money order, past or future services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

***Stock Appreciation Rights*.** Stock appreciation rights are granted under stock appreciation right agreements adopted by the administrator. The administrator determines the purchase price or strike price for a stock appreciation right, which generally will not be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under our 2022 Plan will vest at the rate specified in the stock appreciation right agreement as determined by the administrator. Stock appreciation rights may be settled in cash or shares of our common stock or in any other form of payment as determined by our board of directors and specified in the stock appreciation right agreement.

The administrator determines the term of stock appreciation rights granted under our 2022 Plan, up to a maximum of ten years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate upon the termination date. In no event may a stock appreciation right be exercised beyond the expiration of its term.

***Performance Awards*.** Our 2022 Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, our common stock.

The performance goals may be based on any measure of performance selected by our board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by our board of directors at the time the performance award is granted, our board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

***Other Stock Awards*.** The administrator may grant other awards based in whole or in part by reference to our common stock. The administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

***Non-Employee Director Compensation Limit*.** The aggregate value of all compensation granted or paid to any non-employee director with respect to any fiscal year, including awards granted and cash fees paid by us to such non-employee director, will not exceed $ in total value, except such amount will increase to $ for the first year for newly appointed or elected non-employee directors.

***Changes to Capital Structure*.** In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under our 2022 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

***Corporate Transactions*.** In the event of a corporate transaction (as defined in the 2022 Plan), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant, any stock awards outstanding under our 2022 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full (or, in the case of performance awards with multiple vesting levels depending on the level of performance, vesting will accelerate at 100% of the target level) to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction); and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award, over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out, or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of our common stock.

***Change in Control*.** Stock awards granted under our 2022 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined in the 2022 Plan) as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

***Plan Amendment or Termination*.** Our board of directors has the authority to amend, suspend, or terminate our 2022 Plan at any time, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2022 Plan. No stock awards may be granted under our 2022 Plan while it is suspended or after it is terminated.

2021 Employee Stock Purchase Plan

In , our board of directors adopted, and our stockholders approved, our ESPP. Our ESPP will become effective immediately prior to and contingent upon the execution of the underwriting agreement related to this offering. The purpose of our ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component permits the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws.

***Share Reserve*.** Our ESPP authorizes the issuance of shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each year for a period of ten years, beginning on January 1, 2022 and continuing through January 1, 2031, by the lesser of (i) % of the total number of shares of our common stock outstanding on December 31 of the immediately preceding year; and (ii) shares, except before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii).

***Administration*.** Our board of directors, or a duly authorized committee of our board of directors, administers our ESPP. Our ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under our ESPP, our board of directors may specify offerings with durations of not more than 27 months and to specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. Our ESPP provides that an offering may be terminated under certain circumstances.

***Payroll Deductions*.** Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in our ESPP and to contribute, normally through payroll deductions, a percentage of their earnings (as defined in our ESPP) for the purchase of our common stock under our ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in our ESPP at a price per share that is not less than the lesser of (i) 85% of the fair market value of a share of our common stock on the first day of an offering; or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

***Limitations*.** Employees may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by our board of directors: (i) being customarily employed for more than 20 hours per week; (ii) being customarily employed for more than five months per calendar year; or (iii) continuous employment with us or one of our affiliates for a period of time (not

to exceed two years). No employee may purchase shares under our ESPP at a rate in excess of $25,000 worth of our common stock (based on the fair market value per share of our common stock at the beginning of an offering) for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under our ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to Capital Structure. Our ESPP provides that in the event there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, our board of directors will make appropriate adjustments to: (i) the class(es) and maximum number of shares reserved under our ESPP; (ii) the class(es) and maximum number of shares by which the share reserve may increase automatically each year; (iii) the class(es) and number of shares subject to, and purchase price applicable to, outstanding offerings and purchase rights; and (iv) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. Our ESPP provides that in the event of a corporate transaction (as defined in the ESPP), any then-outstanding rights to purchase our common stock under our ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Plan Amendment or Termination. Our board of directors has the authority to amend or terminate our ESPP, except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Amended and Restated 2017 Equity Incentive Plan

Our board of directors adopted, and our stockholders approved, the AN2 Therapeutics, Inc. Amended and Restated 2017 Equity Incentive Plan, or 2017 Plan, in February 2017. The 2017 Plan was most recently amended in November 2019. The 2017 Plan will be terminated on the date the 2022 Plan becomes effective, and thereafter no further stock awards will be granted under the 2017 Plan. However, any outstanding stock awards granted under the 2017 Plan will remain outstanding, subject to the terms of our 2017 Plan and award agreements, until such outstanding options are exercised or until any stock awards terminate or expire by their terms.

Awards. Our 2017 Plan provides for the grant of incentive stock options, or ISOs, nonstatutory stock options, or NSOs, restricted stock units, stock appreciation rights, restricted stock awards, and other awards. ISOs may only be granted to our employees, including employees of any parent or subsidiary. All other stock awards may be granted to our employees, directors, and consultants, including employees and consultants of any parent or subsidiary.

Authorized Shares. As of December 31, 2020, options to purchase 127,343 shares of our common stock were outstanding, and no shares of our common stock remained available for future issuance under our 2017 Plan. The options outstanding as of December 31, 2020 had a weighted-average exercise price of $0.99 per share. Subject to capitalization adjustments, the maximum

aggregate number of shares of our common stock that may be issued under the 2017 Plan is 1,249,274 shares, and the maximum number of shares issuable pursuant to ISOs is 1,249,274 shares.

***Plan Administration*.** Our board or a duly authorized committee of our board administers our 2017 Plan and the awards granted under it. Under our 2017 Plan, the administrator has the authority to, among other things, determine who will be granted stock awards, to determine the terms and conditions of each stock award (including the number of shares subject to the stock award, when the stock award will vest and, as applicable, become exercisable), to accelerate the time(s) at which a stock award may vest or be exercised, and to construe and interpret the terms of our 2017 Plan and stock awards granted thereunder.

***Options*.** Options granted under our 2017 Plan have terms substantially similar to options that may be granted under our 2022 Plan once it becomes effective.

***Changes to Capital Structure*.** In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, proportionate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under our 2017 Plan, and (ii) the class and number of shares and exercise price or purchase price, if applicable, of all outstanding stock awards.

***Corporate Transactions*.** Our 2017 Plan provides that in the event of a "corporate transaction" (as defined under our 2017 Plan), stock awards outstanding under our 2017 Plan will be treated as provided in the agreement evidencing such acquisition or other combination, which may provide for one or more of the following: (i) acquisition or continuation of outstanding stock awards by the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company); (ii) assignment of reacquisition or repurchase rights we hold to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company); (iii) acceleration of vesting, in whole or in part, of a stock award; (iv) lapse, in whole or in part, of any reacquisition or repurchase rights we hold; (v) cancellation of the stock award to the extent not vested or exercised prior to the effective time of the "corporate transaction" in exchange for cash consideration; and (vi) payment in such form as may be determined by our board equal to the excess, if any, of (A) the value of the property (B) over the applicable exercise price. Our board need not take the same action or actions with respect to all stock awards or portions thereof or with respect to all participants.

***Plan Amendment or Termination*.** Our board has the authority to terminate or amend our 2017 Plan at any time, except any amendment of our 2017 Plan will be subject to stockholder approval if required by applicable law. The termination or amendment of our 2017 Plan will not affect any share previously issued or any stock award previously granted under our 2017 Plan. As described above, our 2017 Plan will be terminated upon the effective date of the 2022 Plan and no future awards will be granted under the 2017 Plan following such termination.

Limitations on Liability and Indemnification

Our amended and restated certificate of incorporation, which will become effective immediately after the closing of this offering, will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation will authorize us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines, and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Plans

Our directors, officers and key employees may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades under parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they do not possess of material nonpublic information, subject to compliance with the terms of our insider trading policy. During the first 180 days from this offering, the sale of any shares under such plan would be subject to the lock-up agreement that the director or officer has entered into with the underwriters.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since our inception and any currently proposed transactions to which we have been or are to be a party in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under the section titled "Executive Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Series A Redeemable Convertible Preferred Stock Financing

In multiple closings held between November 2019 and December 2020, we issued and sold an aggregate of 2,582,403 shares of our Series A redeemable convertible preferred stock at a purchase price of $5.99 per share for an aggregate purchase price of approximately $15.5 million. Our Series A redeemable convertible preferred stock financing included an investment by Anacor of approximately $3.5 million in connection with the license agreement with Anacor.

The following table summarizes the Series A redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

Participants[1]	Shares of Series A Redeemable Convertible Preferred Stock Purchased (#)	Aggregate Purchase Price ($)
Entities affiliated with Adjuvant[2]	834,724	4,999,996.76
Entities affiliated with MGC Venture Partners[3]	262,775	1,574,022.25
Anacor Pharmaceuticals, Inc.[4]	579,064	3,468,593.36
Brii Biosciences Limited[5]	500,834	2,999,995.66
Z Investments, LLC[6]	41,735	249,992.65
Total	**2,219,132**	**13,292,600.68**

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled "Principal Stockholders."

(2) Adjuvant Global Health Technology Fund L.P. and Adjuvant Global Health Technology Fund DE, L.P. (together, Adjuvant) is a holder of 5% or more of our capital stock, and is affiliated with Kabeer Aziz, one of our non-employee directors.

(3) MGC Venture Partners 2018, LP and MGC Venture Partners QP 2018 LP (together, MGC Venture Partners) is a holder of 5% or more of our capital stock, and is affiliated with Rob Readnour, one of our non-employee directors.

(4) Anacor is a holder of 5% or more of our capital stock.

(5) Brii Biosciences is a holder of 5% or more of our capital stock.

(6) Z Investments, LLC is affiliated with Joseph Zakrzewski, one of our non-employee directors.

Series B Redeemable Convertible Preferred Stock Financing

In March 2021, we issued and sold an aggregate of 2,266,661 shares of our Series B redeemable convertible preferred stock at a purchase price of $35.29 per share for an aggregate purchase price of approximately $80.0 million.

The following table summarizes the Series B redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

Participants[1]	Shares of Series B Redeemable Convertible Preferred Stock Purchased (#)	Aggregate Purchase Price ($)
Entities affiliated with Adjuvant[2]	198,333	6,999,972.84
Entities affiliated with MGC Venture Partners[3]	56,666	1,999,972.08
Entities affiliated with RA Capital[4]	850,001	29,999,969.30
Entities affiliated with Biotechnology Value Fund[5]	389,584	13,749,993.29
Total	**1,494,584**	**52,749,907.51**

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled "Principal Stockholders."

(2) Adjuvant is a holder of 5% or more of our capital stock, and is affiliated with Kabeer Aziz, one of our non-employee directors.

(3) MGC Venture Partners is a holder of 5% or more of our capital stock, and is affiliated with Rob Readnour, one of our non-employee directors.

(4) RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund II, L.P. (together, RA Capital) is a holder of 5% or more of our capital stock.

(5) Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., and Biotechnology Value Trading Fund OS, L.P. (together, Biotechnology Value Fund) is a holder of 5% or more of our capital stock.

Employment Agreements and Stock Option Grants to Directors and Executive Officers

We have entered into employment agreements with certain of our named executive officers, and granted stock options to our named executive officers and certain of our directors, as more fully described in the sections titled "Executive Compensation" and "Management—Non-Employee Director Compensation."

Investors' Rights Agreement

In March 2021, we entered into an Amended and Restated Investors' Rights Agreement (the Rights Agreement) with certain holders of more than 5% of our outstanding capital stock, including Adjuvant, MGC, Anacor, Brii Biosciences, RA Capital, and Biotechnology Value Fund, and certain affiliates of our directors.

The Rights Agreement grants to the holders of our outstanding redeemable convertible preferred stock certain rights, including certain registration rights with respect to the registrable securities held by them. See the section titled "Description of Capital Stock—Registration Rights" for additional information. In addition, the Rights Agreement imposes certain affirmative obligations on us, including our obligation to, among other things, (i) grant each holder who holds at least 350,000 shares of our redeemable convertible preferred stock (the Qualified Investors) a right of first offer with respect to future sales of our equity, excluding the shares to be offered and sold in this offering, and grant certain information and inspection rights to such Major Investors. Each of these obligations will terminate in connection with the closing of this offering.

Voting Agreement

In March 2021, we entered into an Amended and Restated Voting Agreement (the Voting Agreement) with certain holders of more than 5% of our outstanding capital stock, including Adjuvant, MGC, Anacor, Brii Biosciences, RA Capital, and Biotechnology Value Fund, and certain affiliates of our directors.

Pursuant to the Voting Agreement, as amended, Adjuvant and MGC, collectively, have the right to designate two members to be elected to our board of directors. See the section titled “Management—Composition of Our Board of Directors.” The Voting Agreement will terminate by its terms in connection with the closing of this offering and none of our stockholders will have any continuing rights regarding the election or designation of members of our board of directors following this offering.

Right of First Refusal and Co-Sale Agreement

In March 2021, we entered into an Amended and Restated Right of First Refusal and Co-Sale Agreement (the Co-Sale Agreement) with certain holders of more than 5% of our outstanding capital stock, including Adjuvant, MGC, Anacor, Brii Biosciences, RA Capital, and Biotechnology Value Fund, and certain affiliates of our directors.

Pursuant to the Co-Sale Agreement, we have a right of first refusal in respect of certain sales of securities by certain holders of our common stock and redeemable convertible preferred stock. To the extent we do not exercise such right in full, the Major Investors are granted certain rights of first refusal and co-sale in respect of such sale. The Co-Sale Agreement will terminate in connection with the closing of this offering.

Limitations on Liability and Indemnification Agreements

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board. In addition, we have entered into or intend to enter into an indemnification agreement with each of our directors and executive officers, which will require us to indemnify them. For more information regarding these agreements, see the section titled “Executive Compensation—Limitations on Liability and Indemnification.”

Policies and Procedures for Transactions with Related Persons

Prior to closing of this offering, we intend to adopt a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock, and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 (or, if less, 1% of the average of our total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, 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.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of December 31, 2021 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each our of named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership before the offering is based on 6,009,446 shares of our common stock outstanding as of December 31, 2021, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into 4,849,064 shares of our common stock in connection with the closing of this offering.

Applicable percentage ownership after the offering is based on shares of common stock outstanding immediately after the closing of this offering, after giving effect to the automatic conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock into an equivalent number of shares of our common stock in connection with the closing of this offering. In computing the number of shares 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, or exercisable within 60 days of December 31, 2021. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o AN2 Therapeutics, Inc., 1800 El Camino Real, Suite D, Menlo Park, California 94027.

Name of Beneficial Owner	Number of Shares Beneficially Owned (#)	Percentage of Shares Beneficially Owned	
		Before Offering (%)	After Offering (%)
Greater than 5% Holders:			
Entities affiliated with Adjuvant Global Health Technology Fund[1]	1,033,057	17.2%	
Entities affiliated with RA Capital Healthcare Fund[2]	850,001	14.1	
Anacor Pharmaceuticals, Inc.[3]	579,064	9.6	
Brii Biosciences Limited[4]	500,834	8.3	
Entities affiliated with Biotechnology Value Fund[5]	389,584	6.5	
Entities affiliated with MGC Venture Partners[6]	319,441	5.3	

Name of Beneficial Owner	Number of Shares Beneficially Owned (#)	Percentage of Shares Beneficially Owned Before Offering (%)	Percentage of Shares Beneficially Owned After Offering (%)
Directors and Named Executive Officers:			
Eric Easom(7)	574,221	9.5%	
Sanjay Chanda, Ph.D.(8)	29,956	*	
Lucy Day(9)	21,461	*	
Kabeer Aziz(10)	1,033,057	17.2	
Gilbert Marks, M.D.(11)	10,962	*	
Patricia Martin(12)	2,951	*	
Rob Readnour, Ph.D.(13)	319,441	5.3	
Stephanie Wong(14)	2,951	*	
Joseph Zakrzewski(15)	268,540	4.5	
All directors and executive officers as a group (11 persons)(16)	2,293,557	37.5%	

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 701,947 shares of common stock issuable upon conversion of Series A redeemable convertible preferred stock and 166,785 shares of common stock issuable upon conversion of Series B redeemable convertible preferred stock held by Adjuvant Global Health Technology Fund L.P. and (ii) 132,777 shares of common stock issuable upon conversion of Series A redeemable convertible preferred stock and 31,548 shares of common stock issuable upon conversion of Series B redeemable convertible preferred 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 L.P. and Adjuvant Global Health Technology Fund DE L.P. Kabeer 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 501 Fifth Avenue, Room 1404, New York, New York 10017.

(2) Consists of (i) 722,501 shares of common stock issuable upon conversion of Series B redeemable convertible preferred stock held by RA Capital Healthcare Fund, L.P. (RA Healthcare) and (ii) 127,500 shares of common stock issuable upon conversion of Series B redeemable convertible preferred stock held by RA Capital Nexus Fund II, L.P. (RA Nexus Fund). RA Capital Management, L.P. (RACM) is the investment manager for RA Healthcare and RA Nexus Fund. The general partner of RACM is RA Capital Management GP, LLC. The general partner of RA Healthcare is RA Capital Healthcare Fund GP, LLC. The general partner of RA Nexus Fund is RA Capital Nexus Fund II GP, LLC. Peter Kolchinsky and Rajeev Shah are the managing members of RA Capital Management GP, LLC, RA Capital Healthcare Fund GP, LLC, and RA Capital Nexus Fund II GP, LLC and have the power to vote or dispose of the shares held by RA Healthcare and Nexus Fund II. The address of the persons and entities listed above is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

(3) Consists of shares of common stock issuable upon conversion of Series A redeemable convertible preferred stock. The principal business address for Anacor Pharmaceuticals, Inc. is c/o Pfizer Inc. 235 East 42nd Street, New York, New York 10017.

(4) Consists of shares of common stock issuable upon conversion of Series A redeemable convertible preferred stock. The principal business address for Brii Biosciences Limited is WeWork One Center, Unit 05-130, 110 Corcoran Street, Durham, North Carolina 27701.

(5) Consists of (i) 209,764 shares of common stock issuable upon conversion of Series B redeemable convertible preferred stock held by Biotechnology Value Fund, L.P. (BVF), (ii) 154,627 shares of common stock issuable upon conversion of Series B redeemable convertible preferred stock held by Biotechnology Value Fund II, L.P. (BVF2), and (iii) 25,193 shares of common stock issuable upon conversion of Series B redeemable convertible preferred stock held by Biotechnology Value Trading Fund OS, L.P. (Trading Fund). BVF I GP LLC (BVF GP) is the general partner of BVF and disclaims beneficial ownership of shares of common stock held by BVF. BVF II GP LLC (BVF2 GP) is the general partner of BVF2 and disclaims beneficial ownership of shares of common stock held by

BVF2. BVF GP Holdings LLC (BVF GPH) is the sole member of each of BVF GP and BVF2 GP and disclaims beneficial ownership of the shares of common stock held in aggregate by BVF and BVF2. BVF Partners OS, Ltd. (Partners OS) is the general partner of the Trading Fund and disclaims beneficial ownership of the shares of common stock held by Trading Fund. BVF Partners L.P. is the investment manager of BVF and disclaims beneficial ownership of the shares of common stock held by BVF, BVF2, and Trading Fund. BVF Inc. is the general partner of, BVF Partners L.P., OS Partners and disclaims beneficial ownership of the shares of common stock held by BVF, BVF2, and Trading Fund. Mark Lampert is a director and officer of BVF Inc. and disclaims beneficial ownership of the shares of common stock held by BVF, BVF2, and Trading Fund. The business address of BVF, BVF GP, BVF2, BVF2 GP, BVF GPH, BVF Partners L.P., OS Partners, BVF Inc., and Mr. Lampert is 44 Montgomery St., 40th Floor, San Francisco, California 94104. The business address of Trading Fund and Partners OS is PO Box 309 Ugland House, Grand Cayman, KY1-1104, Cayman Islands.

(6) Consists of (i) 141,583 shares of common stock issuable upon conversion of Series A redeemable convertible preferred stock and 30,532 shares of common stock issuable upon conversion of Series B redeemable convertible preferred stock held by MGC Venture Partners QP 2018 LP (MGC 2018 QP) and (ii) 121,192 shares of common stock issuable upon conversion of Series A redeemable convertible preferred stock and 26,134 shares of common stock issuable upon conversion of Series B redeemable convertible preferred 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 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.

(7) Consists of (i) 467,500 shares of common stock held by the Easom Living Trust dated August 21, 2019 of which Mr. Easom is a trustee, (ii) 41,250 shares of common stock held by the C. Easom Irrevocable Trust dated October 8, 2021 of which Mr. Easom is a trustee, (iii) 41,250 shares of common stock held by the Jude Easom Irrevocable Trust dated October 8, 2021 of which Mr. Easom is a trustee, (iv) 2,086 shares of common stock held by Mr. Easom issuable upon conversion of Series A redeemable convertible preferred stock, and (v) 22,135 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of December 31, 2021.

(8) Consists of 29,956 shares of common stock that may be acquired by Dr. Chanda pursuant to the exercise of stock options within 60 days of December 31, 2021.

(9) Consists of 21,461 shares of common stock that may be acquired by Ms. Day pursuant to the exercise of stock options within 60 days of December 31, 2021.

(10) Consists of the shares described in footnote (1) above. Mr. Aziz disclaims beneficial ownership of all such shares except to the extent of his pecuniary interests therein.

(11) Consists of (i) 9,703 shares of common stock, 4,327 of which shares will be vested within 60 days of December 31, 2021, and 5,376 of which shares will continue to be subject to our repurchase right and (ii) 1,259 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of December 31, 2021.

(12) Consists of 2,951 shares of common stock that may be acquired by Ms. Martin pursuant to the exercise of stock options within 60 days of December 31, 2021.

(13) Consists of the shares described in footnote (6) above. Dr. Readnour disclaims beneficial ownership of all such shares except to the extent of his pecuniary interests therein.

(14) Consists of 2,951 shares of common stock that may be acquired by Ms. Wong pursuant to the exercise of stock options within 60 days of December 31, 2021.

(15) Consists of (i) 215,000 shares of common stock held by Z3 Trust, of which Mr. Zakrzewski is an affiliate, (ii) 41,735 shares of common stock issuable upon conversion of Series A redeemable convertible preferred stock held by Z Investments, LLC, of which Mr. Zakrzewski is an affiliate, and (iii) 11,805 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of December 31, 2021.

(16) See footnotes 7 through 15 above; also includes Kevin Krause and Paul Eckburg, M.D., who are executive officers but not named executive officers.

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation, which will become effective immediately after the closing of this offering, and the amended and restated bylaws, which will become effective upon the closing of this offering. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will be in effect on the closing of this offering.

Upon filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of shares of common stock, par value $0.00001 per share and shares of preferred stock, par value $0.00001 per share. All of our authorized shares of preferred stock will be undesignated.

As of October 31, 2021, after giving effect to the automatic conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock into an equivalent number of shares of our common stock upon the closing of this offering, there were 6,009,446 shares of common stock outstanding and held of record by 69 stockholders.

Common Stock

Voting Rights

The common stock is entitled to one vote per share on any matter that is submitted to a vote of our stockholders. Our amended and restated certificate of incorporation does not provide for cumulative voting for the election of directors. Our amended and restated certificate of incorporation establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class will be subject to election by a plurality of the votes cast at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified structure of our board of directors, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent, and exclusive jurisdiction.

Economic Rights

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, all shares of common stock will have the same rights and privileges and rank equally, share ratably and be identical in all respects for all matters, including those described below.

***Dividends*.** Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See the section titled “Dividend Policy” for further information.

***Liquidation Rights*.** On our liquidation, dissolution, or winding-up, the holders of common stock will be entitled to share equally, identically, and ratably in all assets remaining after the payment of any

liabilities, liquidation preferences, and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

No Preemptive or Similar Rights

The holders of our shares of common stock are not entitled to preemptive rights, and are not subject to conversion, redemption, or sinking fund provisions.

Fully Paid and Non-Assessable

In connection with this offering, our legal counsel will opine that the shares of our common stock to be issued under this offering will be fully paid and non-assessable.

Preferred Stock

Upon the closing of this offering, all of our currently outstanding shares of redeemable convertible preferred stock will convert into common stock and we will not have any redeemable convertible preferred stock outstanding. Immediately after the closing of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of redeemable convertible preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Stock Options

As of June 30, 2021, 455,868 shares of common stock were issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of $11.77 per share. Subsequent to June 30, 2021 and through December 31, 2021, we granted an additional 219,518 shares of common stock with a weighted-average exercise price of $18.62 per share. Following completion of this offering, shares of our common stock will be reserved for future issuance under the 2022 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under the 2022 Plan and any shares underlying outstanding stock awards granted under the 2017 Plan, that expire or are repurchased, forfeited, cancelled, or withheld. For additional information regarding terms of our equity incentive plans, see the section titled “Executive Compensation—Equity Benefit Plans.”

Registration Rights

Upon the closing of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the conversion of our redeemable convertible

preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our amended and restated investors' rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback, and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback, and Form S-3 registration rights described below will expire no later than three years after the closing of this offering.

Demand Registration Rights

Upon the closing of this offering, holders of an aggregate of shares of our common stock will be entitled to certain demand registration rights. At any time beginning 180 days after the closing of this offering, the holders of % of these shares may request that we register all or a portion of their shares. We are not required to effect more than registration statements which are declared or ordered effective. Such request for registration must cover shares with an anticipated aggregate offering price of at least $ million. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 180 days following the effective date of the registration statement for this offering.

Piggyback Registration Rights

In connection with this offering, the holders of an aggregate of shares of our common stock were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. After this offering, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations.

Form S-3 Registration Rights

Upon the closing of this offering, holders of an aggregate of shares of common stock will be entitled to certain Form S-3 registration rights. Holders of % of these shares can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and if the reasonably anticipated aggregate net proceeds of the shares offered would equal or exceed $ million. We will not be required to effect more than registrations on Form S-3 within any 12-month period.

Anti-Takeover Provisions

The provisions of Delaware law, our amended and restated certificate of incorporation, and our amended and restated bylaws, which are summarized below, may have the effect of delaying, deferring, or discouraging another person from acquiring control of our company. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Certificate of Incorporation and Bylaws to be in Effect in Connection with this Offering

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation, to be effective immediately after the closing of this offering, and our amended and restated bylaws, to be effective on the closing of this offering, will provide for stockholder actions at a duly called meeting of stockholders or, before the date on which all shares of common stock convert into a single class, by written consent. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer or president. Our amended and restated bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors.

As described above in "Management—Composition of Our Board of Directors," in accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms.

The foregoing provisions will make it more difficult for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

When we have a class of voting stock that is either listed on a national securities exchange or held of record by more than 2,000 stockholders, we will be subject to Section 203 of the DGCL which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, subject to certain exceptions.

Choice of Forum

Our amended and restated certificate of incorporation to be effective immediately after the closing of this offering will provide that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time); (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the

validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Our amended and restated certificate of incorporation to be effective on the closing of this offering will further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against an defendant to such complaint. The choice of forum provisions would not apply to claims or causes of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

For the avoidance of doubt, these provisions are intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our amended and restated certificate of incorporation to be effective immediately after the closing of this offering will provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Limitations on Liability and Indemnification

See the section titled "Executive Compensation—Limitations on Liability and Indemnification."

Exchange Listing

Our common stock is currently not listed on any securities exchange. We intend to apply to have common stock approved for listing on The Nasdaq Global Market under the symbol "ANTX."

Transfer Agent and Registrar

On the closing of this offering, the transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC. The transfer agent's address is 48 Wall Street, 22nd Floor, New York, New York 10005.

SHARES ELIGIBLE FOR FUTURE SALE

Before the closing of this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Based on our shares outstanding as of October 31, 2021, upon the closing of this offering, a total of shares of common stock will be outstanding, assuming the automatic conversion of all 4,849,064 shares of our outstanding redeemable convertible preferred stock into an equivalent number of shares of our common stock in connection with the closing of this offering. Of these shares, all of the common stock sold in this offering by us, plus any shares sold by us on exercise of the underwriters' option to purchase additional common stock, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144.

The remaining shares of common stock will be, and shares of common stock subject to stock options will be on issuance, "restricted securities," as that term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Subject to the lock-up agreements described below and the provisions of Rule 144 or Rule 701 under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market after the date of this prospectus.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates, or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares of common stock from us; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 of the Securities Act (Rule 701) generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

Form S-8 Registration Statements

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock that are issuable under our 2017 Plan, 2022 Plan and ESPP. These registration statements will become effective immediately on filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below, and Rule 144 limitations applicable to affiliates.

Lock-up Arrangements

We, and all of our directors, executive officers, and the holders of substantially all of our common stock and securities exercisable for or convertible into our common stock outstanding immediately on the closing of this offering, have agreed with the underwriters that, until 180 days after the date of the underwriting agreement related to this offering, we and they will not (and will not cause or direct any affiliate to), without the prior written consent of the representatives of the underwriters, subject to certain exceptions, directly or indirectly, offer, pledge, sell, contract to sell, assign, transfer, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to purchase, lend or otherwise transfer or dispose of, or announce the intention to otherwise dispose of, any of our shares of common stock, or any securities convertible into or exercisable or exchangeable for shares of our common stock, or enter into, or announce the intention to enter into, any hedging, swap, or similar agreement or arrangement that transfers, is designed to transfer or reasonably could be expected to transfer, in whole or in part, directly or indirectly, the economic consequence of ownership of the securities, whether any such swap or transaction is to be settled by delivery of our common stock or other securities, in cash or otherwise. These agreements are described in “Underwriting.” The representatives of the underwriters may, in their sole discretion, release any of the securities subject to these lock-up agreements at any time.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the amended and restated investors’ rights agreement, our standard form of option agreement and our standard form of restricted stock agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell, or transfer our equity securities for a period of 180 days following the date of this prospectus.

Registration Rights

Upon the closing of this offering, pursuant to our amended and restated investors’ rights agreement, the holders of shares of our common stock, or their transferees, will be entitled to certain rights with respect to the registration of the offer and sale of their shares under the Securities

Act, subject to the terms of the lock-up agreements described under the section titled “—Lock-up Arrangements” above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately on the effectiveness of the registration. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See the section titled “Description of Capital Stock—Registration Rights” for additional information.

CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a summary of certain material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local, or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the IRS, all as in effect on the date of this prospectus. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a non-U.S. holder in light of such non-U.S. holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers, or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who acquire our common stock through the exercise of an option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons subject to the alternative minimum tax;
- persons subject to special tax accounting rules under Section 451(b) of the Code;
- persons that own or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a "U.S. person" or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (i) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust, or (ii) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on Our Common Stock

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. However, if we distribute cash or other property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under "—Gain on Disposition of Our Common Stock" below.

Subject to the discussion below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our withholding agent with a valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying such holder's qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of dividends and must be updated periodically. In the case of a non-U.S. holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of the tax treaty, dividends will be treated as paid to the entity or to those holding an interest in the entity. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such

holder's U.S. trade or business (and are attributable to such holder's permanent establishment or fixed base in the United States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and FATCA (as defined below), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- we are or become a United States real property holding corporation, or a USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), on gain realized upon the sale or other taxable disposition of our common stock which may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. If we are or become a United States real property holding corporation during the period described in the third bullet point above and our common stock is not regularly traded for purposes of

the relevant rules, gain arising from the sale or other taxable disposition of our common stock by a non-U.S. holder will generally be subject to U.S. federal income tax in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI, or certain other requirements are met, and if the payor does not have actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

Withholding on Payment to Certain Foreign Accounts or Entities

Sections 1471 through 1474 of the Code (commonly referred to as FATCA), impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our common stock. The U.S. Treasury Department has released proposed regulations under FATCA providing for the elimination of the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of our common stock. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA will not apply to gross proceeds from sales or other dispositions of our common stock.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

UNDERWRITING

We and the underwriters for the offering named below have entered into an underwriting agreement with respect to the common stock being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of shares of our common stock set forth opposite its name below. Cowen and Company, LLC, SVB Leerink LLC, and Evercore Group L.L.C. are the representatives of the underwriters.

Underwriter	Number of Shares
Cowen and Company, LLC	
SVB Leerink LLC	
Evercore Group L.L.C.	
Oppenheimer & Co. Inc.	
Total	

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased, other than those shares covered by the overallotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel, or modify offers to the public and to reject orders in whole or in part.

Overallotment Option to Purchase Additional Shares. We have granted to the underwriters an option to purchase up to additional shares of common stock at the public offering price, less the underwriting discount. This option is exercisable for a period of 30 days. The underwriters may exercise this option solely for the purpose of covering overallotments, if any, made in connection with the sale of common stock offered hereby. To the extent that the underwriters exercise this option, the underwriters will purchase additional shares from us in approximately the same proportion as shown in the table above.

Discounts and Commissions. The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

We estimate that the total expenses of the offering, excluding underwriting discounts, will be approximately $ and are payable by us. We have also agreed to reimburse the underwriters for expenses of up to $ related to the clearance of this offering with the Financial Industry Regulatory Authority, Inc.

	Per Share	Total Without Over allotment	Total With Over allotment
Initial public offering price			
Underwriting discounts and commissions			
Proceeds before expenses, to us			

The underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus. The underwriters may offer the shares of common stock to securities dealers at the public offering price less a concession not in excess of $ per share. If all of the shares are not sold at the public offering price, the underwriters may change the offering price and other selling terms.

Discretionary Accounts. The underwriters do not intend to confirm sales of the shares to any accounts over which they have discretionary authority.

Market Information. Prior to this offering, there has been no public market for shares of our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In addition to prevailing market conditions, the factors to be considered in these negotiations will include:

- the history of, and prospects for, our company and the industry in which we compete;
- our past and present financial information;
- an assessment of our management;
- our past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

We have applied for the quotation of our common stock on The Nasdaq Global Market under the symbol “ANTX.”

Stabilization. In connection with this offering, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions, penalty bids, and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.
- Overallotment transactions involve sales by the underwriters of shares of common stock in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares overallotted by the underwriters is not greater than the number of shares that they may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the overallotment option. The underwriters may close out any short position by exercising their overallotment option or purchasing shares in the open market.

- Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the overallotment option. If the underwriters sell more shares than could be covered by exercise of the overallotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by that syndicate member is purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Global Market, in the over-the-counter market, or otherwise and, if commenced, may be discontinued at any time.

***Lock-Up Agreements*.** Pursuant to certain “lock-up” agreements, we and our executive officers, directors, and substantially all of our other stockholders, have agreed, subject to certain exceptions, not to (and to not cause or direct any affiliate to) offer, sell, assign, transfer, pledge, contract to sell, lend, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into, or announce the intention to enter into, any swap, hedge or similar agreement or arrangement that transfers, is designed to transfer or reasonably could be expected to transfer, in whole or in part, directly or indirectly, the economic consequence of ownership of, or make any demand or request or exercise any right with respect to the registration of, or file with the SEC a registration statement under the Securities Act relating to, any common stock or securities convertible into or exchangeable or exercisable for any common stock without the prior written consent of the representatives for a period of 180 days after the date of the pricing of the offering.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The exceptions permit us, among other things and subject to restrictions, to: (a) issue common stock or options pursuant to employee benefit plans, (b) issue common stock upon exercise of outstanding options or warrants, or (c) file registration statements on Form S-8.

The exceptions permit our executive officers, directors, and shareholders, as parties to the “lock-up” agreements, among other things and subject to restrictions, to: (a) allow the conversion of our outstanding convertible preferred stock into shares of common stock in connection with the consummation of this offering, (b) make certain gifts, not involving a disposition of value, (c) make transfers to certain trusts, not involving a disposition of value, (d) make transfers by will or intestate succession, not involving a disposition of value, (e) make transfers by operation of law pursuant to order of a court, in connection with a negotiated divorce settlement or pursuant to a qualified domestic relations order, not involving a disposition of value, (f) if the party is a corporation, partnership, limited liability company or other business entity, make transfers to any stockholders, partners, members or

managers of, or owners of similar equity interests in, the party, or to an affiliate of the party or to an investment fund or other entity that controls or manages, is controlled by, or is under common control with the party, if such transfer is not for value, (g) if the party is a corporation, partnership, limited liability company or other business entity, make transfers in connection with the sale or transfer of all or substantially all of the party's capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the party's assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by the "lock-up" agreement, or to another corporation, partnership, limited liability company or other business entity provided the transferee is an affiliate of the party and such transfer is not for value, (h) make transfers pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction, (i) if the party is a trust, make distributions to its beneficiaries in a transaction not involving a disposition of value, provided that no public announcement or filing is made regarding such transaction during the 180-day lock-up period, (j) make transfers or dispositions to us pursuant to any contractual arrangement that provides for the repurchase of the party's common stock or other securities or in connection with the termination of the party's employment or other service relationship with us, (k) enter into transactions relating to shares of common stock or other securities convertible into or exercisable or exchangeable for common stock acquired in this offering or in open market transactions after completion of this offering, provided that no public announcement or filing is made regarding such transaction during the 180-day lock-up period, (l) enter into a 10b5-1 trading plan, provided that such plan does not permit the sale of any common stock during the 180-day lock-up period and no public announcement or filing is made regarding such plan during the 180-day lock-up period, and (m) make transfers to us to satisfy tax withholding obligations pursuant to our equity incentive plans disclosed in this prospectus.

The representatives, in their sole discretion, may release our common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release our common stock and other securities from lock-up agreements, the representatives will consider, among other factors, the holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time of the request. In the event of such a release or waiver for one of our directors or officers, the representatives shall provide us with notice of the impending release or waiver at least three business days before the effective date of such release or waiver and we will announce the impending release or waiver by issuing a press release at least two business days before the effective date of the release or waiver.

Electronic Offer, Sale, and Distribution of Shares. A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other Relationships. Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking, and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees.

Selling Restrictions

Canada. The common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106

Prospectus Exemptions or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area. In relation to each Member State of the European Economic Area (each, a Relevant State), no shares of common stock have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares of common stock which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares of common stock may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares of common stock shall require our company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares of common stock or to whom any offer is made will be deemed to have represented, acknowledged, and agreed to and with each of the underwriters and our company that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares of common stock being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged, and agreed that the shares of common stock acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares of common stock to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares of common stock in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of common stock, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

***United Kingdom*.** No shares of common stock have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares of common stock which has been approved by the Financial Conduct Authority, except that the shares of common stock may be offered to the public in the United Kingdom at any time:

- to any legal entity which is a qualified investor as defined under Article 2 of the U.K. Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the U.K. Prospectus Regulation), subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares of common stock shall require our company or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the U.K. Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares of common stock in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of common stock and the expression "U.K. Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018. In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the U.K. Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the "Order," and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons. Any person in the United Kingdom who is not a relevant person must not act on or rely upon this document or any of its contents.

***Switzerland*.** The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

***Israel*.** In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728 – 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728–1968, including, inter alia, if: (i) the offer is made, distributed, or directed to not more than 35 investors, subject to certain conditions (Addressed Investors); or (ii) the offer is made, distributed, or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728—1968, subject to certain conditions (Qualified Investors). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. Our company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728—1968. We have not and will not distribute this prospectus or make, distribute, or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728—1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify

to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728—1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728—1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728—1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriters and their respective affiliates, with a view to the final placement of the securities as contemplated in this document. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of shares on our behalf or on behalf of the underwriters.

LEGAL MATTERS

The validity of the shares of our common stock being offered in this prospectus will be passed upon for us by Cooley LLP, Palo Alto, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Davis Polk & Wardwell LLP, Menlo Park, California.

EXPERTS

The financial statements as of December 31, 2019 and 2020 and for each of the years in the period ended December 31, 2020 included in this Prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

On the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements, and other information with the SEC. These reports, proxy statements, and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above.

We also maintain a website at www.an2therapeutics.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

AN2 THERAPEUTICS, INC.

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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, 2020 and 2019, and the related statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders’ deficit and of cash flows for the years then ended, including the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits of these financial statements in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

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

/s/ PricewaterhouseCoopers LLP
San Jose, California
September 24, 2021

We have served as the Company’s auditor since 2021.

AN2 Therapeutics, Inc.

Balance Sheets
(in thousands, except share amounts)

	As of December 31, 2019	As of December 31, 2020
Assets:		
Current assets:		
Cash	$ 5,598	$ 4,070
Prepaid expenses and other current assets	102	164
Total current assets	5,700	4,234
Total assets	$ 5,700	$ 4,234
Liabilities, redeemable convertible preferred stock and stockholders' deficit:		
Current liabilities:		
Accounts payable	$ 51	$ 132
Accrued compensation	–	426
Accrued liabilities	108	887
Options subject to repurchase, short-term	–	14
Total current liabilities	159	1,459
Options subject to repurchase, long-term	–	24
Redeemable convertible preferred stock tranche liability	728	–
Total liabilities	887	1,483
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock, $0.00001 par value; 2,590,000 shares authorized at December 31, 2019 and 2020; 1,838,331 and 2,582,403 shares issued and outstanding at December 31, 2019 and 2020, respectively; aggregate liquidation preference of $11,111 and $16,549 at December 31, 2019 and 2020, respectively	10,614	23,070
Stockholders' deficit:		
Common stock, $0.00001 par value; 5,000,000 shares authorized at December 31, 2019 and 2020; 1,085,000 and 1,150,679 shares issued and outstanding at December 31, 2019 and 2020, respectively	–	–
Accumulated deficit	(5,801)	(20,319)
Total stockholders' deficit	(5,801)	(20,319)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 5,700	$ 4,234

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

AN2 Therapeutics, Inc.

Income Statements
(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2019	2020
Operating expenses:		
Research and development	$ 187	$ 5,366
Research and development—related party	4,702	653
General and administrative	289	1,265
Total operating expenses	5,178	7,284
Loss from operations	(5,178)	(7,284)
Interest income	–	3
Other expense	(457)	(6,322)
Net loss	(5,635)	(13,603)
Accretion to redemption value and cumulative dividends on preferred stock	(99)	(981)
Net loss attributable to common stockholders	$ (5,734)	$ (14,584)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.29)	$ (13.36)
Weighted-average number of shares used in computing net loss per share, basic and diluted	1,085,000	1,091,678

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

AN2 Therapeutics, Inc.

Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balances at January 1, 2019	–	$ –	1,085,000	$ –	$ –	$ (67)	$ (67)
Issuance of Series A redeemable convertible preferred stock at $5.99 per share for cash, net of issuance costs of $134	1,371,955	8,084	–	–	–	–	–
Issuance of Series A redeemable convertible preferred stock at a fair value of $5.79 per share in conjunction with vesting of equity instruments granted in the Anacor License	466,376	2,702					
Redeemable convertible preferred stock tranche liability	–	(271)	–	–	–	–	–
Accretion to redemption value and cumulative dividends on preferred stock	–	99	–	–	–	(99)	(99)
Net loss	–	–	–	–	–	(5,635)	(5,635)
Balances at December 31, 2019	1,838,331	10,614	1,085,000	–	–	(5,801)	(5,801)
Issuance of Series A redeemable convertible preferred stock at $5.99 per share for cash, net of issuance costs of $10	631,384	3,772	–	–	–	–	–
Issuance of Series A redeemable convertible preferred stock at a fair value of $5.79 per share in conjunction with vesting of equity instruments granted in the Anacor License	112,688	653					
Settlement of redeemable convertible preferred stock tranche liability	–	7,050	–	–	–	–	–
Issuance of common stock upon exercise of stock options	–	–	65,679	–	–	–	–
Vesting of early exercised stock options	–	–	–	–	26	–	26
Stock-based compensation	–	–	–	–	40	–	40
Accretion to redemption value and cumulative dividends on preferred stock	–	981	–	–	(66)	(915)	(981)
Net loss	–	–	–	–	–	(13,603)	(13,603)
Balances at December 31, 2020	2,582,403	$23,070	1,150,679	$ –	$ –	$ (20,319)	$ (20,319)

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

AN2 Therapeutics, Inc.

Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2019	2020
Cash flows from operating activities:		
Net loss	$(5,635)	$(13,603)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash research and development expense in connection with a license agreement	2,702	653
Stock-based compensation expense	–	40
Change in fair value of redeemable convertible preferred stock tranche liability	457	6,322
Changes in operating assets and liabilities:		
Increase in prepaid expenses and other assets	(102)	(62)
(Decrease) increase in accounts payable	(16)	81
Increase in accrued compensation	–	426
Increase in accrued liabilities	108	779
Net cash used in operating activities	(2,486)	(5,364)
Cash flows from financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	8,084	3,772
Proceeds from exercise of stock options	–	64
Net cash provided by financing activities	8,084	3,836
Net increase (decrease) in cash	5,598	(1,528)
Cash at beginning of period	–	5,598
Cash at end of period	$ 5,598	$ 4,070
Supplemental disclosure of noncash financing items:		
Issuance of redeemable convertible preferred stock in connection with a license agreement	$ 2,702	$ 653
Accretion to redemption value and cumulative dividends on preferred stock	99	981
Redeemable convertible preferred stock tranche liability	271	–

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

AN2 Therapeutics, Inc.

Notes to Financial Statements

1. The Company

Description of Business

AN2 Therapeutics, Inc. (the “Company”) is a biopharmaceutical company focused on developing novel medicines for patients with rare infectious diseases that represent significant unmet needs, specifically its initial product candidate, epetraborole, an antibiotic initially under development as a once-daily, oral treatment for patients with chronic non-tuberculous mycobacterial lung disease. The Company was incorporated in the state of Delaware in February 2017, began operations in November 2019, 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.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, contract manufacturing and contract research organizations, compliance with government regulations and the need to obtain additional financing to fund operations. The Company’s initial product candidate currently under development will require significant additional research and development efforts, including additional clinical trials and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting.

The Company’s initial product candidate is in development. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s in-licensed intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

Liquidity

The Company’s operations have 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 year ended December 31, 2020, the Company incurred a net loss of $13.6 million and had negative net cash flows from operating activities of $5.4 million. The Company has an accumulated deficit as of December 31, 2020 of $20.3 million 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.

Management believes that its cash, including the net cash proceeds of $79.7 million from issuance of its Series B redeemable convertible preferred stock in March 2021 (see Footnote 15) are sufficient to continue operating activities for at least 12 months following 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 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: 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 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.

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").

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.

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 the fair value of common stock and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Research and Development Expenses

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

As part of the process of preparing its financial statements, the Company estimates its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on the Company's behalf and estimating the level of services performed and the associated cost incurred for services for which the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its accrued expenses at the end of each reporting period based on the facts and circumstances known to the Company at that time. The significant estimates in the Company's accrued research and development expenses relate to expenses incurred with respect to contract manufacturing and 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 records the redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs. Upon the occurrence of certain events that are outside the Company's control, including a deemed liquidation event, holders of the redeemable convertible preferred stock can cause redemption for cash. Therefore, the redeemable convertible preferred stock is classified outside of stockholders' deficit on the balance sheet.

The carrying value of the redeemable convertible preferred stock will be adjusted to its redemption value if and when it becomes probable that such a redemption event will occur. Since the holders of the redeemable convertible preferred stock have the right to request the Company to redeem their shares of the redeemable convertible preferred stock after seven years of the issuance, it is probable that the redeemable convertible preferred stock becomes redeemable at the current reporting date. Therefore, the carrying value of the redeemable convertible stock has been accreted to its redemption value.

Redeemable Convertible Preferred Stock Tranche Liability

The redeemable convertible preferred stock issued in November 2019 contained an embedded feature that provides the investors the ability to participate in a second close of the Series A at the same price upon the attainment of a specific milestone. The obligation to issue additional shares of Series A redeemable convertible preferred stock at a future date was determined to be a freestanding instrument that should be accounted for as a liability. At initial recognition, the Company recorded the redeemable convertible preferred stock tranche liability on the balance sheets at its estimated fair value. The redeemable convertible preferred stock tranche liability is subject to remeasurement at each subsequent reporting date, with changes in fair value recognized as a component of other expense. Immediately prior to the settlement of the redeemable convertible preferred stock tranche financing occurring in October 2020, the Company remeasured the redeemable convertible preferred stock tranche liability, with the change in fair value recognized as a component of other expense. The redeemable convertible preferred stock tranche liability was then reclassified to the redeemable convertible preferred stock.

Stock-Based Compensation

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

The valuation model used for calculating the fair value of stock options for stock 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 awards that contain performance conditions, compensation cost is recognized in the period in which it becomes probable that the performance condition will be satisfied. The grant date fair value of these awards is equal to the fair value of the underlying shares as determined by the price other investors paid for such shares in recent transactions. For 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

The absence of an active market for the Company's common stock requires the Company's board of directors to determine the fair value of its common stock for purposes of granting stock options. The fair value of the Company's common stock is determined by the Company's board of directors 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 is 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.

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. As of December 31, 2019 and 2020, the Company had no cash equivalents.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash, which is invested through a financial institution in the United States. Such deposits may be in excess of federally insured limits. 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. Through December 31, 2020, the Company has no off-balance sheet concentrations of credit risk.

Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company recognizes and measures uncertain tax positions using a two-step approach set forth in authoritative guidance. The first step is to evaluate the tax position taken or expected to be taken by determining whether the weight of available evidence indicates that it is more likely than not that the tax position will be sustained in an audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. Significant judgment is required to evaluate uncertain tax positions. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for income taxes includes the effects of any accruals that the Company believes are appropriate. It is the Company's policy to recognize interest and penalties related to income tax matters in income tax expense. Through December 31, 2020, the Company had not accrued interest or penalties related to uncertain tax positions.

On March 18, 2020, the Families First Coronavirus Response Act ("FFCR Act"), and on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property.

On June 29, 2020, Assembly Bill 85 ("A.B. 85") was signed into California law. A.B. 85 provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5.0 million of tax per year. A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021 and 2022 for certain taxpayers with taxable income of $1.0 million or more. The carryover period for any net operating losses that are suspended under this provision will be extended. A.B. 85 also requires that business incentive tax credits including carryovers may not reduce the applicable tax by more than $5.0 million for taxable years 2020, 2021 and 2022.

The FFCR Act, CARES Act and A.B. 85 did not have a material impact on the Company's financial statements as of December 31, 2020; however, the Company continues to examine the impacts the FFCR Act, CARES Act and A.B. 85 may have on its business, results of operations, financial condition, liquidity and related disclosures.

Comprehensive Loss

Comprehensive loss includes net loss and certain changes in stockholders' deficit that are excluded from net loss. The Company has no items of comprehensive income or loss at December 31, 2019 and 2020.

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. 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.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09") and has subsequently issued a number of amendments to Topic 606. As amended, Topic 606 provides a single comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific guidance. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. Topic 606 also requires entities to disclose both qualitative and quantitative information that enables users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers, including disclosure of significant judgments affecting the recognition of revenue. The Company adopted ASU 2014-09 effective January 1, 2019. The adoption did not have a material impact on the Company's financial statements as the Company did not recognize revenue during the period presented.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 amends the FASB ASC to expand the scope of FASB ASC Topic 718, Compensation-Stock Compensation, to include accounting for share-based payment transactions for acquiring goods and services from non-employees. The amendments in ASU 2018-07 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2018. Early adoption was permitted. The Company adopted this guidance effective January 1, 2019. The adoption did not have a material impact on the Company's financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740), which simplifies the accounting for income taxes, primarily by eliminating certain exceptions to ASC 740. This standard is effective for fiscal periods beginning after December 15, 2020 for public business entities, and is effective for all other entities for fiscal periods beginning after December 15, 2021. Early adoption is permitted. The Company adopted this guidance effective January 1, 2019. The adoption did not have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). The amendments on changes in unrealized gains and losses recognized in other comprehensive gains and losses recognized in other comprehensive income categorized within Level 3, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The Company adopted ASU 2018-13 as of January 1, 2020, which did not have a material impact on its financial statements.

Recent Accounting Pronouncements Not Yet Adopted

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 is currently evaluating the impact of the adoption of ASU 2016-02 on its financial statements.

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 all entities except SEC reporting companies that are not smaller reporting companies. The Company is currently evaluating the impact of the adoption of ASU 2016-13 on its financial statements.

3. Fair Value Measurements

The Company records its 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 I: Inputs which include quoted prices in active markets for identical assets and liabilities.
- Level II: 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 III: 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, prepaid expenses, accounts payable, accrued liabilities and redeemable convertible preferred stock tranche liabilities. The carrying amounts of the Company's financial instruments, other than the redeemable convertible preferred stock tranche liability, approximate fair value due to their relatively short maturities. The Company's has no financial assets or liabilities outside of Level III liabilities, which consist entirely of the redeemable convertible preferred stock tranche liability. The Company's fair value measurement of its redeemable convertible preferred stock tranche liability as of December 31, 2019 was $0.7 million. The determination of the fair value of the redeemable convertible preferred stock tranche liability is discussed in Note 9.

The following table sets forth the changes in the fair value of Level III liabilities (in thousands):

	Redeemable Convertible Preferred Stock Tranche Liability
Fair value at December 31, 2018	$ –
Fair value at issuance	271
Change in fair value	457
Fair value at December 31, 2019	728
Change in fair value	6,322
Settlement of redeemable convertible preferred stock tranche liability	(7,050)
Fair value at December 31, 2020	$ –

4. 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 an aggregate 579,064 shares of Series A redeemable convertible preferred stock. For financial reporting purposes the fair value of the shares was $5.79 per share for a total of $3.4 million. The fair value of the shares granted is based on the $5.99 per share price paid by other investors for issued shares in the Series A financing.

The Series A redeemable convertible preferred stock granted to Anacor is accounted for as non-employee awards and is recognized upon the transfer of the license and upon the Company meeting certain operational milestones as included in the Series A Stock Purchase Agreement. For the years ended December 31, 2019 and 2020, 466,376 and 112,688 shares of Series A redeemable convertible preferred stock with a fair value of $2.7 million and $0.7 million, respectively, vested as the related performance and service conditions were satisfied.

The Company recorded the transaction as an asset acquisition as substantially all of the fair value of the gross assets acquired were concentrated in one of the compounds. The assets acquired in the transaction were measured based on the upfront payment and the fair value of the Series A redeemable convertible preferred stock shares issued to Anacor, as the fair value of the consideration given, $5.4 million, was more readily determinable than the fair value of the assets received. As the in-process research and development assets have not yet received regulatory approval and have no alternative future use, the fair value of the assets was recorded as research and development expense—related party. The total amounts recorded in the statements of operations for the years ended December 31, 2019 and 2020 were $4.7 million and $0.7 million, respectively.

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

None of the future development, regulatory, commercial or sales milestones or royalty payments were recognized as of December 31, 2019 and 2020.

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 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.

5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2019	December 31, 2020
Prepaid research and development-related expenses	$ 82	$115
Prepaid insurance	20	39
Prepaid legal expenses	–	10
Total prepaid expenses and other current assets	$ 102	$164

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2019	December 31, 2020
Accrued research and development-related expenses	$ –	$887
Accrued legal expenses	108	–
Total accrued liabilities	$ 108	$887

6. Commitments and Contingencies

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). Adjuvant purchased a total of 834,724 shares of the Company's Series A redeemable convertible preferred stock in 2019 and 2020 for a total investment 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 that Adjuvant ceases to be a shareholder of the Company or, ten years following epetraborole approval for 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 tuberculosis, and melioidosis development activities for the global health programs. The Company has complied with all applicable covenants as of December 31, 2020.

7. Common Stock

The Company's certificate of incorporation, as amended, authorizes the Company to issue 5,000,000 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 of Directors. No dividends have been declared to date.

Common shares reserved for future issuance, on an as-if-converted basis, as of December 31, 2019 and 2020, consists of the following:

	December 31,	
	2019	2020
Series A redeemable convertible preferred stock	1,838,331	2,582,403
Stock options, issued and outstanding	–	127,343
Stock options, authorized for future issuance	155,459	–
Total	1,993,790	2,709,746

8. Redeemable Convertible Preferred Stock

Series A Equity Financing

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 2,590,000 shares of redeemable convertible preferred stock with a par value of $0.00001 per share.

From November 2019 through October 2020, the Company issued a total of 2,003,339 shares of Series A redeemable convertible preferred stock ("Series A") at $5.99 per share for gross proceeds of $12.0 million, and issued 579,064 shares of Series A redeemable convertible preferred stock pursuant to the license agreement between the Company and Anacor, as follows:

The Company entered into a Series A preferred stock purchase agreement (Series A Preferred Stock Purchase Agreement) with certain investors on November 20, 2019 and upon approval by the Company's Board of Directors, the Company completed the first tranche of a Series A redeemable convertible preferred stock financing (Series A—First Tranche) at a price per share of $5.99 for cash. The Company also entered into a license agreement arrangement to license certain compounds and obtain rights to develop, manufacture and commercialize assets acquired under the agreement. An additional 466,376 shares of Series A redeemable convertible preferred stock were issued to Anacor under that certain license agreement (see Note 4). The net cash proceeds from this first tranche of

financing totaled $8.1 million and 1,371,955 shares of Series A redeemable convertible preferred stock were issued. Issuance costs totaled $0.1 million and were recorded as a reduction of the proceeds.

On October 2, 2020, upon achievement of certain research and development milestones outlined in the Series A Preferred Stock Purchase Agreement and upon approval by the Company's Board of Directors, the Company completed a second tranche of the Series A redeemable convertible preferred stock financing (Series A—Second Tranche) at a price per share of $5.99 for cash. The net cash proceeds from this second tranche of financing totaled $3.8 million, and 631,384 shares of Series A redeemable convertible preferred stock were issued. An additional 112,688 shares of Series A redeemable convertible preferred stock were issued to Anacor under that certain license agreement (see Note 4). Issuance costs total $0.01 million and were recorded as a reduction of the proceeds.

At December 31, 2019, 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	2,590,000	1,838,331	$ 5.99	$10,614	$ 11,111

At December 31, 2020, 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	2,590,000	2,582,403	$ 5.99	$23,070	$ 16,549

The rights, preferences, and privileges of the redeemable convertible preferred stock are as follows:

Redemption Rights

Upon the occurrence of certain liquidation events, as well as upon a written request by at least two-thirds of the holders of the Series A redeemable convertible preferred stock on or after the seventh anniversary of the Series A original issue date, redeemable convertible preferred stock must be redeemed by the Company at a price of $5.99 per share plus any accrued dividends (whether or not declared) in three annual installments. During the years ended December 31, 2019 and 2020, the Company accreted $0.1 million and $1.0 million, respectively, to the redemption value of the redeemable convertible preferred stock representing cumulative dividends.

Dividends Rights

Cumulative dividends of $0.4792 per share per annum for each Series A redeemable convertible preferred stock are payable when and as declared by the Company's Board of Directors, or upon the occurrence of a liquidation event or upon a contingent mandatory conversion of the Series A redeemable convertible preferred stock in connection with a qualified initial public offering as described below. The Series A original issue price is $5.99. The original issue price is subject to adjustment in the event of any share dividend, share split, combination, consolidation or other recapitalization. The dividends shall accrue from day to day from the issue date of the Series A redeemable convertible preferred stock whether or not declared and shall be cumulative. In addition, the Series A redeemable convertible preferred stock participates on an as-converted basis in any dividends payable to ordinary shareholders. Cumulative dividends for the years ended December 31, 2019 and 2020 were $0.1 million and $1.1 million, respectively. No dividends have been declared or paid since the initial issuance of redeemable convertible preferred shares through December 31, 2020.

Liquidation Rights

In the event of liquidation, dissolution or winding up of the Company, merger or a reduction of capital through the sale or lease of all or a substantial part of the business of the Company, before any distribution or payment shall be made to the holders of ordinary shares, the holders of preferred shares shall be entitled to be paid an amount in cash equal to the original issue price (subject to adjustment in the event of any share dividend, share split, combination, or other recapitalization) plus all dividends accumulated and unpaid thereon. First, the holders of the preferred shares are paid in full the amounts as specified on a pro-rata basis; then, after holders of the preferred shares are satisfied, any remaining amounts shall be distributed on a pro-rata basis to the holders of the common shares.

Voting Rights

Except as otherwise required by law, the holders of common and Series A redeemable convertible preferred stock vote together as a single class. The holders of the redeemable convertible preferred stock are entitled to the number of votes equal to the number of shares of common stock into which the redeemable convertible preferred stock could be converted on the record date for the vote, or upon the written consent of the stockholders.

The holders of the Series A redeemable convertible preferred stock are entitled to elect two directors of the Company and the holders of common stock shall be entitled to elect two directors of the Company.

Optional Conversion

Each share of redeemable convertible preferred stock shall be convertible, at the option of the holder, into such number of fully paid shares of common stock as is determined by dividing the original issue price by the conversion price in effect at the time of conversion. As of December 31, 2019 and 2020, the initial conversion price per share of redeemable convertible preferred stock is equivalent to the original issue price and as such converts on a one-for-one basis prior to any adjustments.

The respective applicable conversion price is subject to adjustment upon any future stock splits or stock combinations, reclassifications or exchanges of similar stock, upon a reorganization, merger or consolidation of the Company, or upon the issuance or sale by the Company of common stock for consideration less than the applicable conversion price.

Mandatory Conversion

Each share of Series A redeemable convertible preferred stock automatically converts into the number of shares of common stock determined in accordance with the conversion rate upon the earlier of (a) the closing of an initial public offering in at a price per share of common stock at least equal to $17.97 (as may be adjusted for stock splits, reverse splits, stock dividends, combinations, and other recapitalizations) resulting in at least $50 million of net proceeds to the Company after deducting underwriters commissions and expenses or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least two-thirds of the outstanding shares of Series A redeemable convertible preferred stock, then (i) all outstanding shares of redeemable convertible preferred stock shall automatically be converted into shares of Common Stock at the then effective conversion rate and (ii) such shares may not be reissued by the Company. Through December 31, 2020, the Company has sufficient authorized and unissued common shares available to settle any conversion event.

9. Redeemable Convertible Preferred Stock Tranche Liability

The Company's obligation to issue additional shares of its redeemable convertible preferred stock represents a freestanding financial instrument (see Note 2 and Note 3). The freestanding redeemable

convertible preferred stock tranche liability is initially recorded at fair value, with fair value changes recognized as increases or reductions in other expense in the statements of operations. The Company continued to adjust the liability for changes in the estimated fair value until the settlement of the redeemable convertible preferred stock tranche liability. At such time, any remaining value of the redeemable convertible preferred stock tranche liability was reclassified to redeemable convertible preferred stock with no further remeasurement required. The Company had recorded a redeemable convertible preferred stock tranche liability in November 2019 of $0.3 million related to the Series A redeemable convertible preferred stock financing.

The Company estimated the fair value of the redeemable convertible preferred stock tranche liability using a Black-Scholes option pricing model using the following:

- ***Expected term—***The expected term represents the period for which the redeemable convertible preferred stock tranche liabilities are expected to be outstanding, which is estimated to be the remaining contractual term.
- ***Expected volatility—***The volatility data was estimated based on a study of publicly traded industry peer companies, as there is no trading history for the Company's redeemable convertible preferred stock. For purposes of identifying these comparable peer companies, the Company considered the industry, stage of development, size and financial leverage. The Company has measured historical volatility over a period equivalent to the expected term and believes that historical volatility provides a reasonable estimate of future expected volatility.
- ***Expected dividends—***The Black-Scholes option pricing model calls for a single expected dividend yield as an input. The Company currently has no history or expectation of paying cash dividends on its preferred stock.
- ***Risk-free interest rate—***The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the redeemable convertible preferred stock tranche liability.

The Black-Scholes option pricing model resulted in a tranche liability of $0.3 million using the following assumptions: estimated equity value of $14.7 million, a term of 3.5 years, a risk-free rate of 1.59%, a volatility of 82.4%, and a dividend yield of 0.0%.

The redeemable convertible preferred stock tranche liability was remeasured as of December 31, 2019 with the following assumptions: estimated equity value was $19.0 million, a term of 3.5 years, a risk-free rate of 1.56%, a volatility of 89.3% and a dividend yield of 0.0% resulting in a fair value of approximately $0.7 million. The Company recorded the change in fair value of approximately $0.5 million as other expense in the statements of operations for the year ended December 31, 2019.

The redeemable convertible preferred stock tranche liability was settled in October 2020 at the time of the tranche closing of the Series A redeemable convertible preferred stock and the remeasured liability balance of $7.1 million was reclassified to redeemable convertible preferred stock. The final closing fair value was remeasured with the following assumptions: estimated equity value was $63.0 million, a term of 4.1 years, a risk-free rate of 0.23%, a volatility of 112.3% and a dividend yield of 0.0%. The Company recorded the change in fair value of $6.3 million in other expense in the statements of operations for the year ended December 31, 2020.

10. Equity Incentive Plan and Stock-Based Compensation

2017 Equity Incentive Plan

In February 2017, the Board of Directors approved the 2017 Equity Incentive Plan (the Plan). Under the Plan, 293,022 shares of common stock have been reserved for the issuance of ISOs, NSOs,

and rights to acquire restricted stock to employees, officers, directors, and consultants of the Company as of December 31, 2020. The Plan allows for the issuance of non-statutory and incentive stock options (ISOs) to employees and non-statutory stock options (NSOs) to non-employees. ISOs and NSOs may be granted with exercise prices at no less than 100% of the fair value of the common stock on the date of grant. Options granted to a 10% stockholder shall be at no less than 110% of the fair value, and ISO stock option grants to such 10% stockholders expire five years from the date of grant.

The Company permits 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. The shares issued pursuant to unvested options have been included in shares issued and outstanding on the balance sheet and statement of stockholders' equity as such shares are not considered outstanding for accounting purposes.

ISOs granted under the 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. 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.

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:

- ***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 volatility***—Since the Company is privately-held and does not have any 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.
- ***Expected term***—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual term of the stock-based awards.
- ***Expected dividends***—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 fair value of stock options granted to employees, directors and non-employees was estimated using the following weighted-average assumptions:

	Year Ended December 31, 2020
Expected dividend yield	–
Expected term	5.82 years
Risk-free interest rate	1.29%
Expected volatility	79.1%

Management's calculations are based on a grant date valuation approach. Using the Black-Scholes model, the weighted-average grant-date fair value per share for options granted during the year ended December 31, 2020 was $0.67. No options were granted during the year ended December 31, 2019.

Stock Option Plan Activity

A summary of the stock plan activity is as follows:

	Options Available for Grant	Outstanding Options	Weighted Average Exercise Price
Balances at December 31, 2018	–	–	$ –
Reserved	155,459	–	–
Balances at December 31, 2019	155,459	–	–
Reserved	37,563	–	$ –
Granted	(193,022)	193,022	0.99
Exercised(1)	–	(65,679)	0.99
Balances at December 31, 2020	–	127,343	$ 0.99

(1) As of December 31, 2020, 38,976 shares underlying options exercised were subject to repurchase.

For the year ended December 31, 2020, the total intrinsic value of stock option awards exercised was immaterial, determined at the date of option exercise, and the total cash received upon exercise of stock options was $0.06 million. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying stock option awards and the estimated fair value of the common stock on the date of exercise.

Additional information related to the status of options at December 31, 2020, is as follows:

	Options	Weighted Average Exercise Price per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding	127,343	$ 0.99	9.27	$ –
Exercisable	127,343	0.99	9.27	–
Vested and expected to vest	166,321	0.99	9.26	–
Vested and unexercised	32,099	0.99	9.08	–

As of December 31, 2020, there was unrecognized share-based compensation expense of $0.1 million related to unvested share options which the Company expects to recognize over a weighted-average period of 2.9 years. The total fair value of shares vested during the year ended December 31, 2020 was $0.04 million.

Stock-Based Compensation Expense

Total stock-based compensation for all options granted to employees, directors and non-employees, before taxes is as follows (in thousands):

	Year Ended December 31, 2020
Research and development expenses	$ 31
General and administrative expenses	9
Total	$ 40

Liability for Early Exercise of Stock Options

As of December 31, 2020, there were 38,976 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 1/48 of the shares underlying the original grant per month for 36 months thereafter. The shares purchased by the optionholders 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, 2020, the Company recorded $0.04 million as short- term and long-term liabilities associated with the cash received for shares issued subject to repurchase rights.

11. Income Taxes

The Company is liable for income taxes in the United States. For the years ended December 31, 2019 and 2020, 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 difference between the tax at the statutory federal tax rate and no tax provision recorded by the Company is primarily due to the Company's full valuation allowance against its deferred tax assets.

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,	
	2019	2020
Federal tax (benefit) at statutory rate	$(1,183)	$(2,856)
State tax (benefit) at statutory rate, net of federal tax benefit	(370)	(589)
Change in valuation allowance	1,454	2,066
Change in fair value of redeemable convertible preferred stock tranche liability	96	1,328
Other	3	51
Provision for income taxes	$ –	$ –

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 $2.1 million from December 31, 2019 to December 31, 2020 due to generation of current year net operating losses and research and development credits claimed.

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, 2019	December 31, 2020
Deferred tax assets		
Net operating loss carryforwards	$ 1,455	$ 3,428
Tax credit carryforwards	9	91
Other	3	14
Gross deferred tax assets	1,467	3,533
Valuation allowance	(1,467)	(3,533)
Net deferred tax assets	$ –	$ –

As of December 31, 2020, the Company had $12.2 million of federal and $12.4 million of state net operating loss available to offset future taxable income. The state net operating loss carryforwards begin to expire in 2037. The Company also has California research and development credits of $0.1 million, which do not expire.

Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

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. It is possible the Company experienced an ownership change during one of the rounds of funding received since the inception of the Company; however, no formal study has been performed. If it is determined there was an ownership change, the Company's net operating loss and credit carryforwards would be limited by Section 382. The Company is not in a taxable position and no net operating loss carryforwards or credit have been used to date.

The Company has adopted authoritative guidance which prescribes a recognition threshold and measurement attribute to the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in the Company's income tax return, and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

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.

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,	
	2019	2020
Numerator:		
Net loss	$ (5,635)	$ (13,603)
Add: accretion to redemption value and cumulative dividends on preferred stock	(99)	(981)
Net loss attributable to common stockholders	$ (5,734)	$ (14,584)
Denominator:		
Weighted-average common shares outstanding used to calculate net loss per share attributable to common stockholders, basic and diluted	1,085,000	1,091,678
Net loss per share attributable to common stockholders, basic and diluted	$ (5.29)	$ (13.36)

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,	
	2019	2020
Series A—First Tranche redeemable convertible preferred stock	1,838,331	1,868,714
Series A—Second Tranche redeemable convertible preferred stock	–	713,689
Options issued and outstanding	–	127,343
Early exercised common stock subject to future vesting	–	38,976
Total	1,838,331	2,748,722

13. Related Party Transactions

During the years ended December 31, 2019 and 2020, the Company recorded research and development expenses of $4.7 million and $0.7 million, respectively, related to the upfront milestone payment and issuance of redeemable convertible preferred stock in conjunction with the Anacor License. See Note 4 for further discussion.

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 2019 and 2020, the Company did not make a matching contribution.

15. Subsequent Events

The Company evaluated events occurring between the end of the most recent fiscal year and September 24, 2021, the date the financial statements were available to be issued.

Redeemable Convertible Preferred Stock Financing

The Company entered into a Series B redeemable convertible preferred stock purchase agreement with certain investors on March 5, 2021 whereby the Company issued 2,266,661 shares of Series B

redeemable convertible preferred stock at a price per share of $35.29 for cash. The net cash proceeds from this round of financing totaled $79.7 million, net of issuance costs of $0.3 million.

Adjuvant Global Health Agreement Addendum

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 ("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 invested $7.0 million in the Company's Series B redeemable convertible preferred stock financing, 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.

Anacor License Milestone

In June 2021, the Company incurred approximately $0.3 million in research and development expense - related party upon achievement of a development milestone due to Anacor.

Shares

Common Stock

PROSPECTUS

Cowen **SVB Leerink** **Evercore ISI**

Oppenheimer & Co.

Through and including , 2022 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Unless otherwise indicated, all references to "AN2," the "company," "we," "our," "us," or similar terms refer to AN2 Therapeutics, Inc.

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all expenses to be paid by us, other than underwriting discounts and commissions, in connection with this offering. All amounts shown are estimates except for the Securities and Exchange Commission, or the SEC, registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee, and The Nasdaq Global Market, or Nasdaq, listing fee.

	Amount Paid or to Be Paid
SEC registration fee	$ *
FINRA filing fee	*
Nasdaq listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Custodian transfer agent and registrar fees	*
Miscellaneous expenses	*
Total	$ *

* To be provided by amendment.

Item 14. Indemnification of Directors and Executive Officers.

Section 145 of the DGCL authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and executive officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act. Our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering permits indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the DGCL, and our amended and restated bylaws that will be in effect on the closing of this offering provide that we will indemnify our directors and executive officers and permit us to indemnify our employees and other agents, in each case to the maximum extent permitted by the DGCL.

We have entered into indemnification agreements with our directors and executive officers, whereby we have agreed to indemnify our directors and executive officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or executive officer was, or is threatened to be made, a party by reason of the fact that such director or executive officer is or was a director, executive officer, employee, or agent of AN2, provided that such director or executive officer acted in good faith and in a manner that the director or executive officer reasonably believed to be in, or not opposed to, the best interest of AN2.

At present, there is no pending litigation or proceeding involving a director or executive officer of AN2 regarding which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification.

We maintain insurance policies that indemnify our directors and officers against various liabilities arising under the Securities Act and the Securities Exchange Act of 1934, as amended, that might be incurred by any director or officer in his capacity as such.

The underwriters are obligated, under certain circumstances, under the underwriting agreement to be filed as Exhibit 1.1 to this Registration Statement, to indemnify us and our officers and directors against liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding unregistered securities issued by us since January 1, 2018.

(a) Equity Plan-Related Issuances

1. From January 1, 2018, through December 31, 2021, we granted certain of our directors, executive officers, employees, and consultants options to purchase 835,768 shares of our common stock under our 2017 Equity Incentive Plan with per share exercise prices ranging between $0.00001 and $23.61 per share.
2. From January 1, 2018, through December 31, 2021, we issued and sold an aggregate of 160,382 shares of common stock upon the exercise of options under our 2017 Equity Incentive Plan at per share exercise prices ranging from $0.00001 to $0.99, for an aggregate exercise price of $74,629.18.

(b) Other Issuances of Capital Stock

3. In multiple closings held between February 2017 and May 2018, we granted certain of our directors, executive officers, and consultants 1,773,000 shares of restricted common stock with a per share price of $0.00001, for an aggregate purchase price of $17.73.
4. In November 2019, we issued and sold 1,371,955 shares of Series A redeemable convertible preferred stock at a price per share of $5.99, for an aggregate purchase price of approximately $8.2 million.
5. In November 2019, we issued 466,376 shares of Series A redeemable convertible preferred stock to Anacor Pharmaceuticals, Inc., or Anacor, as consideration in connection with entering into a license agreement with Anacor.
6. In January and March 2020, we issued and sold 30,383 shares of Series A redeemable convertible preferred stock at a price per share of $5.99, for an aggregate purchase price of approximately $0.2 million.
7. In October 2020, we issued and sold 601,001 shares of Series A redeemable convertible preferred stock at a price per share of $5.99, for an aggregate purchase price of approximately $3.6 million.
8. In October 2020, we issued 112,688 shares of Series A redeemable convertible preferred stock to Anacor as consideration in connection with a license agreement with Anacor.
9. In March 2021, we issued and sold 2,266,661 shares of Series B redeemable convertible preferred stock at a price per share of $35.29404, for an aggregate purchase price of approximately $80.0 million.

The offers, sales, and issuances of the securities described in paragraphs (1) and (2) were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipients of such securities were our directors, employees, or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business, or other relationships, to information about us.

The offers, sales, and issuances of the securities described in paragraphs (3) through (8) were deemed to be exempt under Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D under the Securities Act as a transaction by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business, or other relationships, to information about us. No underwriters were involved in these transactions.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description
1.1+	Form of Underwriting Agreement.
3.1‡	Amended and Restated Certificate of Incorporation, as currently in effect.
3.2+	Form of Amended and Restated Certificate of Incorporation, to be in effect immediately after the closing of the offering.
3.3‡	Amended and Restated Bylaws, as currently in effect.
3.4+	Form of Amended and Restated Bylaws, to be in effect immediately after the closing of the offering.
4.1+	Form of Common Stock Certificate.
4.2‡	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated March 5, 2020.
5.1+	Opinion of Cooley LLP.
10.1‡#	AN2 Therapeutics, Inc. 2017 Equity Incentive Plan, as amended.
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.
10.3+#	AN2 Therapeutics, Inc. 2022 Equity Incentive Plan.
10.4+#	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the AN2 Therapeutics, Inc. 2022 Equity Incentive Plan.
10.5+#	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the AN2 Therapeutics, Inc. 2022 Equity Incentive Plan.
10.6+#	AN2 Therapeutics, Inc. 2022 Employee Stock Purchase Plan.
10.7+#	AN2 Therapeutics, Inc. 2022 Non-Employee Director Compensation Policy.
10.8+#	AN2 Therapeutics, Inc. Officer Severance Plan.
10.9+#	Form of Indemnification Agreement by and between the Registrant and its directors and executive officers.
10.10+#	Offer Letter by and between the Registrant and Eric Easom, dated November 19, 2019.
10.11+#	Offer Letter by and between the Registrant and Lucy Day, dated November 19, 2019.

10.12+#	Offer Letter by and between the Registrant and Sanjay Chanda, dated November 19, 2019.
10.13+*	License Agreement by and between the Registrant and Anacor Pharmaceuticals, Inc., dated November 20, 2019, as amended on December 3, 2021.
10.14+*	License Agreement by and between the Registrant and Brii Biosciences Limited, dated November 20, 2019.
10.15+*	Amended and Restated Global Health Agreement with Adjuvant Global Health Technology Fund L.P. and Adjuvant Global Health Technology Fund DE L.P., dated March 5, 2021.
23.1+	Consent of independent registered public accounting firm.
23.2+	Consent of Cooley LLP (included in Exhibit 5.1).
24.1+	Power of Attorney (included on signature page).

+ To be filed by amendment.

‡ Previously filed.

# 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.

(b) Financial Statement Schedules.

All financial statement schedules are omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant under the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1) or (4) or 497(h) under the Securities Act will be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus will be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time will be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Menlo Park, State of California on , 2022.

AN2 THERAPEUTICS, INC.

By: _____
Name: Eric Easom
Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Eric Easom, Lucy Day, and Michael Nazak and each one 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 their name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by this registration statement that is to be effective on filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and all post-effective amendments thereto, 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 might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Eric Easom	Chief Executive Officer and Director (Principal Executive Officer)	, 2022
Lucy O. Day	Chief Financial Officer (Principal Financial Officer)	, 2022
Michael Nazak	Vice President and Controller (Principal Accounting Officer)	, 2022
Joseph Zakrzewski	Chair and Director	, 2022
Kabeer Aziz	Director	, 2022

Gilbert L. Marks	Director	, 2022
Patricia (Patty) Martin	Director	, 2022
Rob Readnour	Director	, 2022
Stephanie Wong	Director	, 2022