



# 2022 Annual Report

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

FORM 10-K

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 001-396147



**TARSUS**

**TARSUS PHARMACEUTICALS, INC.**

(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

81-4717861  
(I.R.S. Employer  
Identification Number)

15440 Laguna Canyon Road, Suite 160  
Irvine, California  
(Address of principal executive offices)

92618  
(Zip Code)

(949) 409-9820  
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	TARS	The Nasdaq Global Market LLC (Nasdaq Global Select Market)

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

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

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by an of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the registrant's common stock as reported by the Nasdaq Global Select Market on June 30, 2022, was approximately \$180.5 million. Shares of common stock held by each executive officer, director, and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 9, 2023, the number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, was 26,731,663.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the information called for by Part III of this Annual Report on Form 10-K is hereby incorporated by reference to portions of the registrant's definitive proxy statement for its 2023 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2022.

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#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of 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. Factors that may cause actual results to differ from expected results include, among others:

- our ability to obtain regulatory approval and successfully commercialize TP-03 for the treatment of Demodex blepharitis;
- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates, and other positive results;
- the timing and progress of our current clinical trials and timing of initiation of our future clinical trials, and the reporting of data from our current and future trials;
- the timing or likelihood of regulatory filings and approval for our product candidates;
- our plans relating to the clinical development of our current and future product candidates, including the size, number and disease areas to be evaluated;
- the prevalence of Demodex blepharitis and the size of the market opportunity for our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- our plans relating to commercializing our product candidates, if approved, including sales strategy;
- the impact of health epidemics, including COVID-19, on our business and operations;
- the success of competing therapies that are or may become available;
- our estimates of the number of patients in the United States ("U.S.") or globally, as applicable, who suffer from Demodex blepharitis, Meibomian Gland Disease, rosacea, Lyme disease and malaria and the number of patients that will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates and our product candidates to meet existing or future regulatory standards;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications for which we may pursue;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the expected potential benefits of strategic collaborations with third parties (including, for example, the receipt of payments, achievement and timing of milestones under license agreements, and the ability of our third party collaborators to commercialize our product candidates in the territories under license) and our ability to attract collaborators with development, regulatory and commercialization expertise;
- existing regulations and regulatory developments in the U.S. and other jurisdictions;

- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- the need to hire additional personnel, in particular sales personnel, and our ability to attract and retain such personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- our competitive position;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the proceeds from our Initial Public Offering and subsequent follow-on public offerings, and credit facility.

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 growth prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions, including those described in the section titled "Risk Factors" elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements after the date of this Annual Report on Form 10-K, whether as a result of any new information, future events or otherwise.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this report and the documents that we reference in this report and have filed with the SEC as exhibits to this report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the "Company", "we," "us," "our," "Tarsus," and "Tarsus Pharmaceuticals" refer to Tarsus Pharmaceuticals, Inc. We primarily conduct our business activities as Tarsus Pharmaceuticals.

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Tarsus Pharmaceuticals, Tarsus, and Tarsus Pharmaceuticals, Inc., our logo and other registered or common law trade names, trademarks or service marks of Tarsus appearing in this report are the property of the Company. This report contains additional trade names, trademarks and service marks of other companies that are the property of their respective owners. We

do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies. Solely for convenience, our trade names, trademarks and service marks referred to in this report appear without the ®, ™ or SM 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 right of the applicable licensor to these trade names, trademarks and service marks.

#### SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

We face risks and uncertainties associated with our business, many of which are beyond our control. Some of the more significant risks associated with our business include the following:

- We are a biopharmaceutical company with limited operating history. We have incurred significant losses and negative cash flows from operations since our inception and anticipate that we will continue to incur significant expenses and losses for the foreseeable future.
- We may need to obtain additional funding to complete the development and any commercialization of our product candidates, if approved. If we are unable to raise this necessary capital when needed, we would be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.
- We are heavily dependent on the success of our lead product candidate, TP-03 for the treatment of Demodex blepharitis. If we are unable to successfully obtain regulatory approval for, or commercialize, TP-03, or experience significant delays in doing so, our business will be materially harmed.
- Even if TP-03 or any other product candidate that we develop receives marketing approval, we may not be successful in educating eye care physician ("ECPs"), and the market about the need for treatments specifically for Demodex blepharitis and other diseases or conditions targeted by our product candidates, and TP-03 or other product candidates that we may develop may fail to achieve market acceptance by ECPs, other healthcare providers and patients, or adequate formulary coverage, pricing or reimbursement by third-party payers and others in the medical community, and the market opportunity for these products may be smaller than we estimate.
- The sizes of the market opportunity for our product candidates, particularly TP-03 for the treatment of Demodex blepharitis and MGD, have not been established with precision and may be smaller than we estimate, possibly materially. If our estimates of the sizes overestimate these markets, our sales growth may be adversely affected. We may also not be able to grow the markets for our product candidates as intended or at all.
- The development and commercialization of our products, including our lead product candidate, TP-03 for the potential treatment of Demodex blepharitis and Meibomian Gland Disease ("MGD"), TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme prophylaxis and community malaria reduction, is dependent on intellectual property we license from Elanco Tiergesundheit AG ("Elanco").
- We will need to develop and expand our company and we may encounter difficulties in managing our growth, which could disrupt our operations.
- We contract with third parties for the manufacture of our product candidates for preclinical studies, clinical trials and for eventual commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or compounds or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results.
- Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and

commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

- Patent terms may be inadequate to protect our competitive position on our product candidates and preclinical programs for an adequate amount of time.
- The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

## PART I

### Item 1. Business

#### Overview

We are a biopharmaceutical company focused on the development and commercialization of therapeutics, starting with eye care. Our lead product candidate, TP-03 (lotilaner ophthalmic solution, 0.25%), is a novel investigational eye drop to treat blepharitis caused by the infestation of Demodex mites, which is referred to as Demodex blepharitis. Blepharitis ("Blephar" is a reference to eyelid and "Itis" is a reference to inflammation) is an ophthalmic lid margin disease characterized by inflammation of the eyelid margin, redness and ocular irritation, including a specific type of eyelash dandruff called collarettes, which are pathognomonic for Demodex blepharitis. Poorly controlled and progressive blepharitis can lead to corneal damage over time and, in extreme cases, blindness. There are an estimated 25 million people in the U.S. who suffer from Demodex blepharitis.

We designed TP-03 to target and eradicate the root cause of Demodex blepharitis – Demodex mite infestation. The active pharmaceutical ingredient ("API") of TP-03, lotilaner, paralyzes and eradicates mites and other parasites through the inhibition of parasite-specific gamma-aminobutyric acid-gated chloride ("GABA-Cl") channels.

We intend to further advance our pipeline with lotilaner API to address several diseases across therapeutic and/or prophylactic categories in human medicine, including eye care, dermatology, and other diseases. We are investigating the development of product candidates to address targeted diseases with high unmet medical needs, which currently include TP-03 for the potential treatment of MGD, TP-04 for the potential treatment of rosacea, and TP-05 for potential Lyme disease prophylaxis and community malaria reduction.

#### ***TP-03 for the Potential Treatment of Demodex Blepharitis***

We designed TP-03 to target and eradicate the root cause of Demodex blepharitis – Demodex mite infestation. The API of TP-03, lotilaner, paralyzes and eradicates mites as well as other parasites through the inhibition of parasite-specific GABA-Cl channels.

To date, we have completed seven clinical trials for TP-03 in Demodex blepharitis that include a Phase 1 trial (the "Hyperion trial"), four Phase 2 trials, a Phase 2b/3 trial (the "Saturn-1 trial"), and the Phase 3 trial (the "Saturn-2 trial"). Each of these trials for TP-03 met primary, secondary and/or certain exploratory endpoints, with the drug well tolerated. In November 2022, we announced that the New Drug Application ("NDA") submission package for TP-03 for the treatment of Demodex blepharitis was accepted by the U.S. Food and Drug Administration ("FDA"), with a stated Prescription Drug User Fee Act ("PDUFA") decision date of August 25, 2023. We believe TP-03 has the potential to be the first therapeutic approved by the FDA and become the definitive standard of care for the treatment of Demodex blepharitis.

#### ***TP-03 for the Potential Treatment of Meibomian Gland Disease (MGD)***

We are also exploring the therapeutic potential of TP-03 for a second ophthalmic condition, MGD, commonly characterized as a clogging or destruction of the meibomian glands that secrete a substance that helps stabilize the ocular surface and can result in tear film deficiency, and is one of the leading causes of dry eye disease. There are no FDA-approved therapeutics for MGD. In the U.S., MGD prevalence has been found to be approximately two-thirds of the estimated 34 million dry eye patient population. One species of Demodex mite, *Demodex brevis*, is known to infest the meibomian gland, and clinical signs of MGD have been shown to be correlated with infestation of *Demodex brevis* and/or decreasing inflammation of the eye lid due to Demodex.

In August 2022, we announced the enrollment of our first patient in the Phase 2a clinical trial (the "Ersa trial") studying TP-03 for the treatment of MGD in patients with Demodex blepharitis. We expect to report topline data from the Ersa trial during the second half of 2023.

#### ***TP-04 for the Potential Treatment of Rosacea***

Rosacea is a chronic skin disease characterized by facial redness, inflammatory lesions, burning and stinging, which can flare up in response to certain triggers such as sun exposure or emotional stress. According to the U.S. National Rosacea Society, approximately 16 million people in the U.S. are affected by rosacea and rosacea prevalence can represent up to 5.4% of the global population. We conducted a Phase 1 clinical study with TP-04 and initiated a Phase 2a trial (the "Galatea trial") in March 2023, for the treatment of TP-04, a novel gel formulation of lotilaner, for the treatment of rosacea.

### ***TP-05 for the Potential Prevention of Lyme Disease***

In December 2022, we announced positive topline results from the completed Phase 1 Callisto trial (the "Callisto trial") and enrollment of the first patient in the Phase 2a clinical trial (the "Carpo trial"). The Callisto and Carpo trials are designed to evaluate TP-05, a novel investigative oral, non-vaccine prophylactic for the potential prevention of Lyme disease. The Callisto trial was a randomized, double-blind, single and multiple-ascending dose trial that evaluated the safety, tolerability, and pharmacokinetics ("PK") of TP-05 in healthy subjects. Results from the trial showed that TP-05 was well tolerated with no dose-related or drug-related serious adverse events. PK data from the trial demonstrated rapid absorption and an extended half-life of TP-05 that potentially supports a convenient oral therapy regimen, supporting its potential as a rapid onset, prophylactic therapy for Lyme disease. Additionally, an exploratory ex-vivo tick kill study that utilized serum from TP-05 treated subjects demonstrated potent, rapid killing of adult and nymph ticks. The Carpo trial, evaluating TP-05 for the potential prevention of Lyme disease in humans, is a randomized, double-blind trial that will evaluate the efficacy of TP-05 in killing lab grown, non-disease carrying ticks after they have attached to the skin of healthy volunteers, as well as confirm the safety, tolerability, and blood concentration of TP-05. We expect to report topline data from the Carpo trial during the second half of 2023.

We are investigating the development of TP-05 as an oral formulation that is designed as a prophylactic against Lyme disease to eradicate the tick before it can transmit the *Borrelia burgdorferi* infection. There are approximately 80 million people in the U.S. at risk of Lyme disease exposure, more than 27 million of which are at moderate to high risk and there are greater than 400,000 reported cases in the U.S. each year, which is believed to be an underestimation of the actual cases. Lyme disease can potentially cause severe, often debilitating symptoms with permanent and irreversible damage. The disease can result in inflammation, nerve, joint and muscle pain or swelling, numbness, shortness of breath and - in severe cases neurological complications such as facial palsy, vision issues and meningitis, including severe headaches and neck stiffness. Lyme disease can often go undetected and untreated because the ticks are not always noticed before they transmit the disease. People who are in high risk areas and/or spend extended amounts of time outdoors in wooded, grassy areas are at higher risk of contracting the infection. Data from the Centers for Disease Control and Prevention ("CDC") show that the risk of Lyme disease is spreading to new geographical areas, resulting in a significant need for prophylactic solutions. Currently, there are no FDA-approved pharmacological prophylactic options for Lyme disease. We believe TP-05 is currently the only non-vaccine, drug-based, preventive therapeutic in development that targets the ticks, and potentially prevents Lyme disease transmission. It is designed to rapidly provide systemic blood levels of lotilaner, a well-characterized anti-parasitic agent that paralyzes and kills infected ticks attached to the human body before they can transmit the *Borrelia burgdorferi* infection that causes Lyme disease. The ticks are paralyzed and eradicated by lotilaner through selective targeting of parasite-specific GABA-Cl channels.

The following pipeline chart presents our wholly-owned product candidates and clinical development status:

Figure 1: Pipeline Chart



WW Worldwide  
 EU European Union  
 OUS Outside the U.S.

**Our Strategy**

Our goal is to transform the treatment of Demodex blepharitis with a first ever FDA approved pharmaceutical therapeutic, and to develop our pipeline of innovative therapies that target certain parasite-mediated diseases with large market opportunities. We intend to achieve these goals by pursuing the following key strategic objectives:

- **Advance TP-03 to eventual approval for the treatment of Demodex blepharitis.** In February 2022, we completed enrollment of our second and final TP-03 pivotal trial, the Saturn-2 trial. In May 2022, we announced positive topline results of the Saturn-2 trial, which enrolled 412 adults having, among other things, more than ten collarettes per lid and at least mild lid erythema. All pre-specified primary and secondary endpoints were met, TP-03 was well tolerated and complete resolution of Demodex blepharitis was demonstrated in patients treated with TP-03 (lotilaner ophthalmic solution, 0.25%). We utilized the data from the Saturn-2 and Saturn-1 trials to support the submission of our NDA with the FDA for TP-03 for the treatment of Demodex blepharitis. In November 2022, we announced the acceptance of our NDA by the FDA, with a stated PDUFA decision date of August 25, 2023.
- **Educate ECPs and establish our own specialty sales organization to commercialize TP-03 in the U.S.** If approved by the FDA for Demodex blepharitis, we intend to commercialize TP-03 by developing our own sales organization targeting a subset of the approximately 15,000 prescribing ECPs in the U.S. Our commercialization efforts will include educating ECPs on the simplicity and speed of diagnosing Demodex blepharitis through a standard eye examination.
- **Expand the eye care applications of TP-03 for other indications, including MGD.** Similar to blepharitis, MGD may also be caused by Demodex infestation, and we intend to explore TP-03 in this indication. We plan to advance the Ersa trial for MGD, with topline results expected during the second half of 2023.

- **Continue to advance and expand our pipeline, bringing novel products utilizing lotilaner to unmet needs across human medicine, including rosacea and, Lyme disease prophylaxis.** The mechanism of lotilaner coupled with our insights into disease where it can demonstrate clinical benefit, provides an opportunity to expand into new indications for treatment or prevention. In December 2022, we announced positive topline data from the Callisto trial, designed to evaluate TP-05 for potential Lyme disease prophylaxis. The topline data showed that TP-05 is well tolerated and that safety data supports progression to the Phase 2a Carpo trial, which we initiated in December 2022. Topline data from the Carpo trial is expected in the second half of 2023. We initiated the Galatea trial for the potential treatment of rosacea in March 2023.
- **Evaluate and selectively enter collaborations to maximize the potential of our pipeline and the scope of our eye care product offerings.** Apart from the recent out-license agreement (the "China Out-License Agreement") with LianBio Ophthalmology Limited ("LianBio") of TP-03 for the treatment of Demodex blepharitis and MGD within the China Territory as noted above, we have retained our rights globally to all of our indications for use in humans, including our lead product candidate, TP-03, for the potential treatment of Demodex blepharitis and MGD, TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme disease prophylaxis and community malaria reduction. Given the potential to treat patients worldwide we may opportunistically enter into additional strategic collaborations around certain product candidates, disease and/or geographic regions.

#### **Blepharitis: Market Overview**

Blepharitis is a common, chronic ophthalmic lid margin disease characterized by inflammation of the eyelid margin, redness and ocular irritation. It is also a progressive disease that often manifests with more severe symptoms if left untreated, such as blurring of vision, missing eyelashes, corneal damage and potentially, in extreme cases, blindness. We believe that the number of Demodex blepharitis patients in the U.S. may be as high as approximately 25 million based on Trattler W, et al. Clin Ophthalmol. 2022;doi:10.2147/OPTH.S354692 (Titan study), indicating approximately 58% of patients presenting to eye care clinics have collarettes and that at least 45 million people annually visit an eye care clinic as reported by Saydah et al. JAMA Ophthalmol. 2020;138(5):479-489.doi:10.1001/jamaophthalmol.2020.0273. In addition, there is growing awareness among ECPs of the pathognomonic sign of Demodex infestation called collarettes or cylindrical dandruff; which is a specific type of debris found at the base of the eyelashes. Collarettes are composed of partially digested epithelial cells, mite waste products and eggs among other things and can be easily diagnosed by ECPs as part of a standard eye examination. The prevalence of Demodex blepharitis increases progressively with aging, which is one main risk factor for the disease, though other frequently presenting patients can also suffer from dry eye, contact lens intolerance, and cataracts. These patients commonly present to the offices of ECPs for other ophthalmic diseases besides blepharitis, such as cataract surgery evaluation and contact lens discomfort. Accordingly, we believe that there is significant opportunity to increase the diagnosis rate of Demodex blepharitis through ECP and patient education that encourages examination of the disease in standard practice.

Despite the high prevalence of patients with Demodex blepharitis and growing awareness of the disease amongst ECPs, there are no FDA-approved therapeutics for the treatment of blepharitis let alone Demodex blepharitis. Although we believe blepharitis and Demodex blepharitis are significantly under-diagnosed diseases, with limited treatment alternatives, there are already approximately 1.5 million annual Demodex blepharitis diagnoses in the U.S. based on findings from a U.S. prevalence study (the "Titan study") and data that show blepharitis classified per the International Classification of Diseases, Tenth Revision, Clinical Modification ("ICD-10-CM"). Demodex blepharitis is currently treated with a variety of over-the-counter remedies such as tea tree oil, lid wipes and artificial tears, as well as off-label prescription products, which often show sub-optimal efficacy, are poorly tolerated and may lead to significant irritation and dissatisfaction for patients. Furthermore, these treatments do not typically eradicate the Demodex mites, which are the root cause of Demodex blepharitis.

We have conducted epidemiology and market research on the prevalence of blepharitis and potential adoption of TP-03. Our research indicates approximately 58% of patients presenting to ECP offices have collarettes and, based on Gao et al. (2005): High Prevalence of Demodex in Eyelashes with Cylindrical Dandruff. Invest Ophthalm and Vis Sci, September 2005, Vol. 46, No. 3089-3094 (the "Gao Study"), all patients with collarettes were also found to have Demodex mites. In addition, our market research suggests the potential for a high level of adoption of TP-03, if approved. In our surveys, we interviewed approximately 250 ECPs, over 90% of whom indicated they would prescribe an FDA approved prescription therapy as a first-line treatment for Demodex blepharitis. Further, patients continue to have underlying risk of Demodex infestation, as there could be a recurrence or reinfestation based on the presence of Demodex mites in the facial pores even after eradication of Demodex mites from the eyelid. Our Phase 2 data from the Mars clinical trial (evaluated the safety and efficacy of TP-03 with a 28-day twice per day ("BID"), dosing regimen, with exploratory endpoints including collarette grade and mite density) and Phase 2b Jupiter clinical trial (a randomized, controlled double-blind trial with mite density and collarette grade as primary and secondary endpoints, respectively) followed patients to one year after four week treatment and showed meaningful recurrence of Demodex blepharitis within six to nine months, which increased considerably one year after treatment. Additionally, the results from the observational extension study of the Phase 2b/3 Saturn-1 trial (the "Saturn-1 Extension study"), showed meaningful collarette reduction in 63% of the patients at one year following a six week treatment. We believe there is a



significant opportunity to increase the diagnosis rate of Demodex blepharitis and build a significant new market with the potential approval of a therapy that addresses the underlying cause of the disease.

## Blepharitis Overview

### Blepharitis

Blepharitis is a common chronic ophthalmic lid margin disease, which may lead to or exacerbate ocular surface disease. Blepharitis is characterized by inflammation of the eyelid margin, redness and ocular irritation, and is primarily diagnosed and treated by ECPs, including ophthalmologists and optometrists. Typical signs and symptoms of blepharitis include debris on the eyelashes, redness of the eye and eyelid, missing or misdirected eyelashes, blurring of vision, irritation, lid itchiness and ocular discomfort. Blepharitis is challenging to manage, recurs frequently, and its progression can lead to scarring of the eyelid, loss of proper eyelid and tear-film function, eyelid and lash abnormalities, inflammation of the conjunctiva and surrounding skin, suboptimal surgical outcomes, corneal damage, and potentially in extreme cases, blindness. Further, according to studies we have conducted, approximately 56% of cataract patients have Demodex infestation, which may increase the risk for infection after cataract and refractive surgery. Therefore, treating Demodex blepharitis may potentially improve patient satisfaction with cataract and refractive surgery. Additionally, the primary reason people stop wearing contact lenses is due to discomfort; blepharitis has been shown to cause contact lens intolerance. Therefore, treating Demodex blepharitis may reduce contact lens intolerance. We believe these benefits may lead to better vision and improved activities of daily living for patients.

Multiple factors can cause blepharitis, including infestation by Demodex mites, bacterial infection, clogging of the meibomian glands and seborrheic dermatitis.

The following images illustrate representative eyelids with Demodex blepharitis demonstrating the characteristic sign of collarettes:



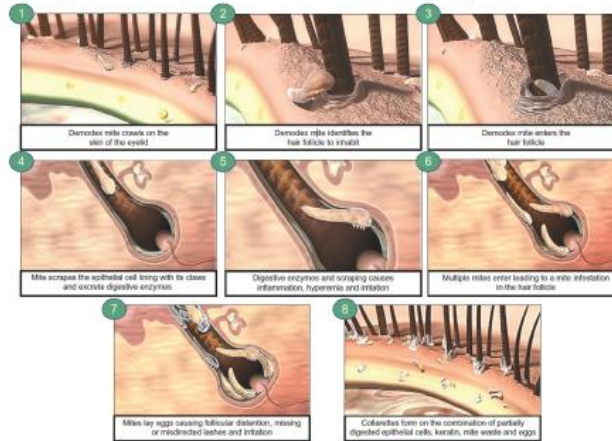
### Demodex Blepharitis

Demodex infestation is a major cause of blepharitis, and we estimate that the number of Demodex blepharitis patients in the U.S. may be as high as approximately 25 million. Although we believe blepharitis and Demodex blepharitis are significantly under-diagnosed diseases, with limited treatment options, there are already an estimated 1.5 million annual Demodex blepharitis diagnoses in the U.S. based on the Titan study and coding for blepharitis classified per the ICD-10-CM. Demodex mites are the most common ectoparasite found on humans and are more likely to cause infestation and disease with aging. Demodex blepharitis typically presents bilaterally in patients with the disease. There are two species of Demodex, *folliculorum* and *brevis*, that live on the skin of the face and eyelids. *Demodex folliculorum*, which is commonly found in the follicle, is the more common sub-species of mite that causes Demodex blepharitis.

The pathognomonic sign of Demodex blepharitis is a specific type of eyelid debris known as the collarette, which is also sometimes referred to as cylindrical dandruff or waxy scurf. Collarettes are composed of partially digested epithelial cells, mite waste products and eggs among other things and can be easily diagnosed by ECPs with a standard eye examination known as the slit lamp examination. Other bothersome signs and symptoms of Demodex blepharitis that can lead to further disease progression include missing or misdirected eyelashes, crusting, redness of the lid margin, inflammation of the lid margin, inflammation of the conjunctiva and/or inflammation of the cornea, also known as blepharoconjunctivitis and blepharokeratitis. Demodex blepharitis is a progressive disease that often manifests with more severe signs and symptoms if left untreated, such as blurring of vision, missing eyelashes, corneal damage and potentially, in extreme cases, blindness. Furthermore, Demodex blepharitis can negatively impact daily activities and create an emotional burden for individuals with the disease.

The following figures illustrate how *Demodex folliculorum* mites enter and reside in the eyelash follicles:

**Figure 3: Demodex folliculorum Mites Entering and Residing in Eyelash Follicles**



Demodex infestation can lead to Demodex blepharitis in three main ways:

- 1) **Mechanical:** Overcrowded mites scrape the epithelial cell lining of the eyelash follicles with their claws and lay eggs, causing follicular distention, misdirected lashes, eyelash loss and irritation. Dead mites and collarettes also obstruct the hair follicle opening, leading to inflammation.
- 2) **Chemical:** Mites excrete digestive enzymes as they feed and exude digestive waste when they die, resulting in inflammation, redness, irritation and epithelial hyperplasia.
- 3) **Bacterial:** Bacteria living on the mite surface or in its gut may cause inflammation of the surrounding ocular tissues. As mites scratch and feed on the skin, the partially digested epithelial cells, keratin, mite waste and eggs combine to form collarettes. These collarettes are typically found at the base of the lash but can migrate away as the hair shaft grows.

The following figure illustrates collarettes at the base of an eyelash:

**Figure 4: Collarettes Are the Pathognomonic Sign of Demodex Blepharitis**



The Gao study confirmed the pathognomonic relationship of the collarette to Demodex infestation. The study included 55 patients seen at the Ocular Surface Center in Miami, Florida to determine the prevalence of Demodex in eyelashes with collarettes. All patients underwent a routine, complete eye examination and external photography. Patients were divided into three main groups: those with collarettes; those without collarettes and those who had been using daily lid scrubs for a full year; and as well as those without collarettes who were not using daily lid scrubs. Of the thirty-two patients in the study, 100% of patients with at least one collarette had Demodex present. Those patients without collarettes were divided into two groups; patients who were using lid scrubs for a full year and those who were not. Only 7% (n=15) of patients without collarettes and who were not performing the daily lid scrubs had Demodex, while 50% (n=8) of those subjects without collarettes, but who were using daily lid scrubs with shampoo for a full year, had Demodex infestation, implying that hygiene alone did not eradicate the mites. All 55 patients were seen at one location and may not be representative of the U.S. population. However, subsequent studies including the two TP-03 pivotal Saturn studies that had >800 patients, consistently demonstrate a correlation between the presence of collarettes and Demodex mites.

Demodex blepharitis can be diagnosed by ECPs with a slit lamp examination, by confirming the presence of collarettes. The slit lamp examination is routinely performed by ECPs as part of standard practice during a customary eye examination, so diagnosing Demodex blepharitis via presence of collarettes would not involve any additional equipment, training or workflow alterations on the part of the ECP.

#### **Current Treatment Options and Their Limitations**

Demodex blepharitis is currently treated with a variety of over-the-counter remedies such as tea tree oil, lid wipes and artificial tears, as well as off-label prescription products for dry eye.

These approaches have significant limitations, including:

- limited efficacy of over-the-counter and off-label treatments as well as device-based treatments administered in clinic by ECPs;
- insufficient definitive knowledge of diagnostic criteria to guide treatment decisions;
- prohibitive side effects (significant burning and stinging) from treatments that target Demodex mites (e.g. tea tree oil);
- current treatments do not typically eradicate the Demodex mites, leading to a chronic and progressive disease; and
- some treatments may be harmful (e.g. to meibomian gland epithelial cells).

According to the Titan real-world prevalence study, 75% of patients using tea tree oils and 57% of those using lid wipes were found to have a high prevalence of collarettes, indicating that current management tools for this disease are largely ineffective. The Titan study was an IRB-approved, retrospective chart review of 1,032 patients across six U.S.-based ophthalmology and optometry practices conducted by seven investigators. The study was designed to better understand the prevalence of Demodex blepharitis via collarettes in U.S. eye care clinics.

#### **Our Approach: Treating Demodex Mites, a Root Cause of Disease**

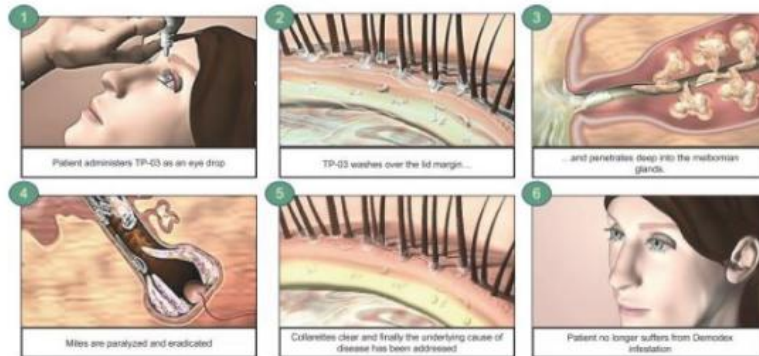
To address these limitations and high unmet need for effectively treating Demodex blepharitis, we are developing TP-03, formulated as an eye drop, which we believe, if approved, has the potential to become the standard of care for Demodex blepharitis. TP-03 is a novel therapeutic based on the drug, lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific GABA-Cl channels. To date, TP-03 has successfully met the primary and secondary endpoints, as applicable, in the completed Phase 2b/3 Saturn-1 and Phase 3 Saturn-2 randomized, placebo controlled pivotal trials, as well as each of the four completed Phase 2 trials. TP-03 was generally well tolerated throughout these trials. As a result, we believe that TP-03 has the potential to be the first ever approved therapeutic for Demodex blepharitis.

**TP-03 Eye Drops – Mechanism of Action**

The active ingredient in TP-03 eye drops is lotilaner, a member of a new class of anti-parasitic molecules called isoxazolines. It is a potent non-competitive antagonist of insect and arachnid GABA-Cl channels. Lotilaner is designed to eradicate Demodex mites by selectively inhibiting GABA-Cl channels, causing mite paralysis and eventual death. It has demonstrated no binding to human GABA-Cl and other ion channels (e.g. hERG) and thus likely has no known impact on the human nervous system. Lotilaner is a lipophilic molecule, which may promote its uptake in the oily sebum of the hair follicle, where the mites reside. In clinical trials, TP-03 is topically applied to the eye twice daily to ensure delivery of the drug to the eyelid margin. Following mite eradication, collarettes eventually clear from the eyelid since they are composed of mite-related waste.

The following figures illustrate the intended paralysis of mites in the hair follicle by TP-03 administration:

**Figure 5: Progression of TP-03 Application, Mite Paralysis and Eradication**



**Clinical Development Program**

To date we have completed one Phase 1 trial, four Phase 2 trials, one Phase 2b/3 trial, and one Phase 3 trial for TP-03 in Demodex blepharitis, all of which met primary, secondary and/or certain exploratory endpoints, while demonstrating the drug was well tolerated. The TP-03 pivotal trial results (Phase 2b/3 and 3) supported the TP-03 NDA package submitted to the FDA for the treatment of Demodex blepharitis, and in November 2022, we announced the acceptance of our NDA submission package by the FDA with a PDUFA decision date of August 25, 2023.

**The Saturn-2 Trial**

In May 2021, we initiated the Saturn-2 trial. It was a randomized, controlled, multicenter, double-masked trial studying the safety and efficacy of TP-03 for the treatment of Demodex blepharitis. The Saturn-2 trial was similar in design and size to Saturn-1, which met the primary and all secondary endpoints. The Saturn-2 trial's primary endpoint was the proportion

of patients achieving collarette cure, defined as zero to two collarettes per lid. Secondary endpoints included the eradication of Demodex mites and the proportion of patients achieving a cure based on a composite of collarette cure and erythema cure (eyelid redness). A statistically significant outcome for primary efficacy endpoints is typically one of the requirements for FDA approval of a product. A statistically significant outcome indicates that the probability of the outcome occurring at random is less than the pre-established allowed error level, frequently set at 0.05 (or 1 in 20).

In May 2022, we announced positive topline results of the Saturn-2 trial, our second TP-03 pivotal trial. The Saturn-2 trial enrolled 412 adults having, among other things, more than ten collarettes per lid and at least mild lid erythema. All pre-specified primary and secondary endpoints were met, TP-03 was well tolerated and complete resolution of Demodex blepharitis was demonstrated in patients treated with TP-03 (lotilaner ophthalmic solution, 0.25%).

**Primary Endpoint:**

- 56% of patients on TP-03 achieved complete collarette cure, defined as zero to two collarettes per lid at day 43, compared to 13% on vehicle (p<0.0001).

**Secondary Endpoints:**

- 52% of patients on TP-03 achieved mite eradication defined as zero mites per lash at day 43, compared to 15% on vehicle (p<0.0001).
- 31% of patients on TP-03 compared to 9% of patients on vehicle (p<0.0001) achieved complete lid erythema cure at day 43.
- 19% of patients on TP-03 achieved a complete composite cure, based on achieving both complete collarette cure and complete lid erythema cure, compared to 4% on vehicle (p<0.0001) at day 43.

**Safety Profile:**

- Consistent with the results from Saturn-1, Saturn-2 demonstrated that TP-03 was well tolerated with a safety profile similar to the vehicle group.
  - 91% of TP-03 patients reported that the drop comfort was neutral to very comfortable.
  - There were no serious treatment-related adverse events nor any treatment-related adverse events leading to treatment discontinuation.

**Additional Analysis:**

- 89% of patients on TP-03 achieved a clinically meaningful collarette reduction, defined as zero to ten collarettes per lid at day 43 compared to 33% of those on vehicle (p<0.0001).

**The Saturn-1 Trial**

The Saturn-1 trial was a randomized, controlled, multi center, double-masked Phase 2b/3 trial that evaluated the safety and efficacy of TP-03 in adults with Demodex blepharitis. In September 2020, we commenced the Saturn-1 trial and completed enrollment of 421 patients aged 18 and over having more than ten collarettes on the upper lid and at least mild erythema of the upper eyelid margin. Each patient had at least 1.5 mites per lash on the upper and lower eyelids combined. One drop of TP-03 was self-administered twice per day in each eye for six weeks. Enrolled patients received no treatment for blepharitis symptoms (i.e. lid hygiene) during the trial or 14 days prior to enrollment. The primary endpoint was complete collarette cure (grade zero defined as - zero to two collarettes per lid) and the secondary endpoints included complete mite eradication (mite density of zero mites per lash) and composite cure (the presence of zero to two collarettes on the upper eyelid and the absence of erythema (redness)).

In June 2021, we announced positive results of the Saturn-1 trial. The pre-specified primary and secondary endpoints were met, and complete resolution of Demodex blepharitis signs (e.g. grade zero collarettes) was demonstrated in patients treated with TP-03 (lotilaner ophthalmic solution, 0.25%).

44% of patients on TP-03 achieved the primary endpoint of complete collarette reduction at day 43 compared to 7% on vehicle (p<0.0001). 81% of patients achieved a significant, clinically meaningful collarette count reduction defined as zero to ten collarettes per lid at day 43 compared to 23% of those on vehicle (p<0.0001). Additionally, a significant, clinically meaningful collarette reduction was seen in 23% of patients on TP-03 compared to 11% on vehicle as early as day 8 (p=0.0003).



The secondary endpoint of complete mite eradication achieved statistically significant results by day 15, and 68% of patients on TP-03 achieved mite eradication compared to 18% on vehicle ( $p < 0.0001$ ) at day 43.

For composite cure, 13.4% of patients on TP-03 achieved a complete cure based on a composite endpoint of collarette cure and erythema cure compared to 1.0% on vehicle ( $p < 0.0001$ ) at day 43. Results for complete erythema cure (19% of patients on TP-03 compared to 7% of patients on vehicle,  $p < 0.0001$ ) and one grade or more erythema improvement (45% of patients on TP-03 compared to 28% of patients on vehicle,  $p = 0.0002$ ) were also statistically significant. Additionally, 92% of TP-03 patients reported that the drop comfort was neutral to very comfortable. There were no serious treatment-related adverse events nor any treatment-related adverse events leading to treatment discontinuation.

In July 2021, we presented additional data from the Saturn-1 Trial at the American Society of Cataract and Refractive Surgery 2021 Annual Meeting demonstrating high treatment response rates, and reinforcing the potential of TP-03 to be the standard of care for Demodex blepharitis patients.

- 95% of TP-03 patients showed a significant improvement in mite count, achieving  $\leq 0.5$  mites per lash
- 93% of TP-03 patients improved by at least one collarette grade

We also announced results from an additional Saturn-1 safety analysis, which reinforced TP-03's positive profile, revealing that TP-03 had no clinically significant adverse effect on multiple safety measures including Corrected Distance Visual Acuity ("CDVA"), corneal staining, and intraocular pressure ("IOP"), and no significant findings from slit lamp biomicroscopy or fundus exam in the study. In addition, no impact to endothelial cell density ("ECD") was demonstrated in a subset of 21 patients. ECD was further evaluated as part of the Saturn-2 trial plan and also demonstrated no impact. We believe that the results from our Saturn-1 trial, along with previously announced data, reinforce TP-03's potential, if approved.

#### **Phase 2 Clinical Trials**

We have completed four Phase 2 clinical trials to date, along with one additional ex vivo study, which included our Mars, Jupiter, Io, and Europa clinical trials. Key efficacy endpoints for our Mars and Jupiter clinical trials included collarette grade and mite density and key efficacy endpoints for our Io and Europa clinical trials included collarette cure rate based on collarette grade, which we refer to herein as collarette cure rate, and mite eradication rate. TP-03 met its primary, secondary and/or certain exploratory endpoints, as applicable, in such trials, and showed statistically significant cure and eradication rates in Io and Europa. TP-03 was generally well tolerated throughout these trials.

#### **Commercial Strategy for Demodex Blepharitis Launch**

If approved, we plan to commercialize TP-03 in the U.S. with a specialty sales force, social and digital media, and ECP education campaigns to targeted prescribing ophthalmologists and optometrists. In our work with key opinion leaders and various associations to increase Demodex blepharitis awareness and education, we have highlighted prevalence, impact, and simplicity of diagnosis of Demodex blepharitis. Our goal is to educate ECPs about the prevalence of Demodex blepharitis, simplicity and efficient diagnosis and the positive profile of our products. In addition to educating ECPs, we believe that patient awareness and identification is important and plan to increase awareness through education and marketing efforts directed toward patients.

Consistent with our goal to educate ECPs, we have recently hired a field medical team that is actively communicating with our key ECPs across the country. We have also launched a physician facing disease education campaign geared at increased disease awareness and encouraging ECPs to more proactively diagnose Demodex blepharitis by incorporating eyelid screening as part of their routine exams.

#### **Development of TP-03 for Meibomian Gland Disease (MGD)**

Beyond Demodex blepharitis, we intend to explore the clinical potential for TP-03 in MGD, a chronic abnormality of the meibomian glands, which are glands on the inner part of the eyelid that secrete lipids and other molecules that are critical to maintaining a healthy tear film on the surface of the eye. MGD is commonly characterized in part by a widespread clogging or destruction of the meibomian glands that can result in tear film deficiency and is one of the leading causes of dry eye disease. In the U.S., MGD prevalence has been found to be approximately two-thirds of the estimated 34 million dry eye patient population. One species of Demodex mite, *Demodex brevis*, is known to infest the meibomian gland, and clinical signs of MGD have been shown to be correlated with *Demodex brevis* infestation. While dry eye is a multi-factorial disease, TP-03 is designed to relieve some of the key elements that may be contributing to MGD by virtue of causing the death of the *Demodex brevis* mites as well as decreasing the inflammation of the eyelid caused by Demodex blepharitis. In August

2022, we announced the enrollment of our first patient in the Phase 2 Ersar trial studying TP-03 for the treatment of MGD. We expect to report topline results during the second half of 2023.

There are no FDA-approved therapeutics for MGD, which is currently treated with a variety of over-the-counter remedies such as tea tree oil, lid wipes and artificial tears, as well as off-label prescription products for dry eye. MGD is also treated with in-office device procedures for gland expression (de-clogging) by an ECP. Despite these existing treatments, there is still a significant need for an effective prescription therapeutic in MGD.

The following figures illustrate a representation of Demodex mites infesting the meibomian gland:

**Figure 6: Demodex Mites Infesting the Meibomian Gland**



#### Our Additional Product Candidates

##### TP-04 Topical Formulation for the Treatment of Rosacea

###### *Rosacea*

Rosacea is a chronic skin disease characterized by facial redness, inflammatory lesions, burning and stinging, which can flare up in response to certain triggers such as sun exposure or emotional stress. According to the U.S. National Rosacea Society, approximately 16 million people in the U.S. are affected by rosacea and a study estimates rosacea prevalence can represent up to 5.4% of the global population. There are two phenotypes for rosacea: patients who present with papulopustular rosacea ("PPR"), and patients who do not (non-PPR), with approximately 55% of patients presenting with the PPR phenotype and 45% presenting with the non-PPR phenotype. According to primary research we conducted with dermatologists, of patients who are being treated with topicals for rosacea, an estimated 18% of overall rosacea patients are seeking treatments, with PPR patients generally more likely to seek treatment given the noticeable symptoms.

The cause of rosacea remains multifactorial but there is increasing evidence that Demodex mites play a role in the disease. Studies have found a correlation between Demodex infestation and rosacea, with a higher density of Demodex mites found in the skin of rosacea patients than in controls. A proposed theory suggests that the *Bacillus oleronius* bacteria has a pathogenic role, contributing to skin inflammation and the signs and symptoms of rosacea; these bacteria are also known to be sensitive to the antibiotics typically prescribed to treat rosacea. Meanwhile, Demodex mites have been shown to carry *Bacillus oleronius* in their digestive tracts, suggesting that Demodex may contribute to rosacea by being a transporter for the bacteria that causes the disease. Furthering that point, there is evidence to suggest that *Bacillus oleronius* forms a symbiotic relationship with Demodex, and that both species must be present in order to cause the signs and symptoms of rosacea. Other bacteria such as *Staphylococcus epidermidis*, also potentially carried by Demodex mites, may play a role in the disease as well.

###### *Current Treatment Options and Their Limitations*

Rosacea is currently treated through topical anti-parasitic creams like ivermectin and other topicals including azelaic acid, and antibiotics like metronidazole, as well as other therapies such as alpha agonists. An estimated 50% of rosacea patients are on at least one prescription topical treatment. A current standard of care, is an anti-parasitic drug composed of 1% ivermectin cream, but is only modestly effective, takes 8 to 12 weeks to show efficacy and is around approximately \$700 wholesale acquisition cost for a 30-day supply.

Other available products include Galderma's Epsolay, a topical cream containing 5% encapsulated benzoyl peroxide and Journey Medical Corporation's Zilxi, a topical foam containing 1.5% minocycline is being commercialized for the treatment of Subtype II rosacea, characterized by small, dome-shaped erythematous papules that resemble acne but are associated with burning and stinging sensations.

While current treatments can address the symptoms of the disease by reducing redness and decreasing papules and pustules, for the majority of patients, complete clearance of these features is not currently achievable and there still exists an unmet medical need.

#### ***Our Approach: TP-04 Topical Formulation for Rosacea***

To address this unmet need in the rosacea market, lotilaner is being developed as a topical dermatology product, TP-04, initially for the treatment of a more severe form of rosacea, PPR. It is designed to be active after topical administration in skin with no systemic activity. Lotilaner's mechanism of targeting and killing Demodex mites has been established through our preclinical study and clinical trials evaluating TP-03 in Demodex blepharitis, which is why we believe it may be effective in another Demodex driven disease. We believe we can improve upon existing treatments in the market, like ivermectin cream (Soolantra), with an API that is potentially more effective (longer half-life, more lipophilic, greater therapeutic window). We believe a longer half-life leads to a more durable and long-lasting treatment and that more lipophilicity is expected to provide better bioavailability in the sebum in the follicle and sebaceous glands where mites reside, thus increasing the opportunity to target and eradicate mites and a greater therapeutic window. We further believe there is potential for TP-04 to be evaluated in combination with topical anti-inflammatory agents or vasoconstrictors.

We have completed the initial preclinical studies for TP-04 and have selected a topical formulation for early clinical studies. We intend to leverage systemic preclinical data from our TP-03 program (such as embryofetal development studies, genotoxicity studies and safety pharmacology studies, and augment with the dermal toxicology studies. We plan to evaluate whether TP-04 is safe and effective at treating the symptoms of PPR in the Galatea study, a Phase 2a trial being conducted in Canada, and in March 2023 announced the initiation of this trial. Prior to commencing clinical trials in the U.S. for TP-04, we will need to obtain an investigational new drug application ("IND") from the FDA.

#### **TP-05 Oral Formulation for the Potential Prophylactic Protection against Lyme Disease**

##### ***Lyme Disease***

Lyme disease is the most common vector-borne disease in the U.S., caused by infection of Borrelia bacteria following bite by a tick vector, predominantly ticks of the Ixodes genus (namely Ixodes scapularis in the U.S.). There are approximately 80 million people in the U.S. at risk of Lyme disease exposure, over 27 million of which are at moderate to high risk and there are greater than 400,000 reported cases in the U.S. each year, which is believed to be an underestimation of the actual cases. We estimate a greater than \$1.3 billion impact to the U.S. healthcare system as a result of Lyme disease. Lyme disease occurs most commonly in geographical areas where the Ixodes scapularis tick is prevalent, namely in the Northeast and Mid-Atlantic regions of the U.S., but also in other regions of the U.S. Lyme disease also occurs in certain parts of Europe, typically resulting from a different Ixodes species vector.

The mechanism of Lyme disease infection is well understood. Borrelia bacteria colonizes the salivary glands of the ticks, and the infected saliva is transmitted to the human host when a tick attaches to a person for feeding. The transfer usually occurs at the conclusion of the feeding and therefore, the probability of Borrelia transmission, and thus the risk of Lyme disease, increases with the duration of the tick's attachment. Borrelia is rarely transferred during the first or even second day of feeding but transfers quite efficiently during and after the third day of feeding (>48 hours). This window from the time of bite to the time of transmission offers an opportunity for intervention to prevent Lyme disease if the tick can be killed prior to the transfer of the Borrelia bacteria.

Lyme disease can be a serious condition that may affect multiple organ systems and produce a broad range of symptoms. Early symptoms include a localized rash, fever and fatigue. More severe, sometimes chronic, symptoms may evolve as the infection spreads, including fever, muscle and joint pain, peripheral and central neurological deficits and lymphocytic meningitis. Lyme disease can be successfully treated with oral antibiotics when diagnosed sufficiently early, but chronic symptoms can commonly persist beyond antibiotic treatment. Because many people are either undiagnosed or misdiagnosed, the treatment of Lyme disease with antibiotics may be commonly delayed or absent.



### **Current Lyme Prophylaxis Options and Their Limitations**

Lyme disease is currently prevented through behavior modification – avoiding areas where ticks are prevalent, wearing clothing which minimizes tick exposure, using insect repellants, and physically removing ticks that have attached. With the exception of removing attached ticks, none of these approaches prevents the transmission of *Borrelia* post-bite.

Moreover, there are currently no FDA-approved small molecules or biologics for the prevention of Lyme disease. A vaccine for Lyme disease, LYMERix, was developed and launched by SmithKline Beecham in 1999. Approximately 1.5 million doses of the vaccine were sold in 1999, but the product was quickly pulled from the market following negative press and a class-action litigation claiming a dangerous side effect profile. We are aware of a second vaccine currently under development by Valneva in partnership with Pfizer for Lyme disease, VLA-15, an mRNA-based vaccine being developed by Yale University, and a pre-exposure prophylaxis injectable therapy being developed by MassBiologics involving a human anti-Lyme monoclonal antibody.

### **Our Approach: TP-05 Oral Formulation for the Prophylactic Protection against Lyme Disease**

Since *Borrelia* is usually transferred during the second or third day following a tick bite, our approach is to eradicate the tick before it can transmit the bacteria. To do this, we are developing TP-05 as an oral formulation of lotilaner. We are targeting potentially at least 30 days of prophylactic protection against Lyme disease with a simple oral regimen of TP-05. Given that lotilaner was developed specifically, in part, to eradicate ticks with systemic administration to domesticated animals such as dogs or cats, the pharmacology of lotilaner for Lyme prophylaxis is well understood. Similar to its mechanism against *Demodex* mites, lotilaner is a potent non-competitive antagonist of tick GABA-Cl channels. Antagonism of these channels in ticks induces paralysis and eventual death. The high selectivity for insect and arachnid GABA-Cl channels over human channels where there has been no demonstrated binding, is a highly advantageous part of the profile of the molecule. Extensive preclinical systemic toxicology and safety pharmacology studies have been performed by third parties to date and support advancing TP-05 into clinical development. Lotilaner has a long, approximate 30-day systemic half-life in dogs, which we believe could provide for a convenient oral administration.

In December 2022, we announced positive topline results from the Phase 1 Callisto trial for TP-05, a novel, oral, non-vaccine therapeutic for the prevention of Lyme disease. The Callisto trial was a randomized, double-blind, single and multiple-ascending dose trial that evaluated the safety, tolerability, and PK of TP-05 in healthy subjects. Results from the trial showed that TP-05 was well tolerated with no dose-related or drug-related serious adverse events. Pharmacokinetic data from the trial demonstrated rapid absorption and an extended half-life of TP-05 that potentially supports a convenient oral regimen supporting its potential as a rapid onset, prophylactic therapy for Lyme disease. Additionally, exploratory ex-vivo tick kill modeling that utilized serum from TP-05 treated subjects demonstrated potent, rapid killing of adult and nymph ticks. In December 2022, we also announced the initiation of the Carpo trial, evaluating TP-05 for the potential prevention of Lyme disease in humans. The Carpo trial is a randomized, double-blind trial that will evaluate the efficacy of TP-05 in killing lab grown, non-disease carrying ticks after they have attached to the skin of healthy volunteers, as well as confirm the safety, tolerability, and blood concentration of TP-05.

There are currently no FDA-approved pharmacological prophylactic options for Lyme disease. We believe TP-05 is currently the only non-vaccine, drug-based, preventive therapeutic in development designed to kill ticks to potentially prevent Lyme disease transmission. It is designed to rapidly provide systemic blood levels of lotilaner, a well-characterized anti-parasitic agent potentially sufficient to paralyze and kill infected ticks attached to the human body before they can transmit the *Borrelia burgdorferi* infection that causes Lyme disease.

### **Chemistry, Manufacturing and Controls ("CMC")**

We do not currently own or operate and currently have no plans to establish facilities for manufacturing, storing, distributing or testing our product candidates. We rely and expect to continue to rely for the foreseeable future on contract manufacturing organizations ("CMOs") to manufacture and supply our preclinical and clinical materials to be used during the development of our product candidates. We have assembled a team of employees and consultants to oversee our technical quality and CMOs.

The product candidate TP-03 includes the lotilaner, API, formulated into a topical eye drop formulation. Only one dose strength of TP-03 is currently being developed, 0.25% lotilaner solution.

We believe that the existing capacity of our current API supplier will be sufficient to support commercial scale-up, validation and commercial launch activities if TP-03 is approved. Our current supplier currently manufactures current good manufacturing practice ("cGMP") lotilaner at multiple geographically distinct facilities.

Although we have relied on a single supplier for both non-clinical and clinical supply for lotilaner under cGMP protocols and a single CMO to manufacture TP-03 and to perform analytical testing services, it is our intent to identify and qualify additional manufacturers to provide lotilaner and drug product manufacturing and analytical testing services. The drug product manufacturing is a compounding and aseptic filling operation that we believe could be transferred to additional CMOs as necessary. We have identified suppliers for TP-04 topical formulation for rosacea and TP-05 oral formulation for Phase 1/2 trials for Lyme disease.

Our third-party service providers, our third-party supply chain providers, their facilities and the TP-03 used in our clinical trials or for commercial sale are required to be in compliance with the requirements of cGMP. The cGMP regulations govern manufacturing processes and procedures, including requirements relating to organization of personnel, buildings and facilities, equipment, control of components and packaging containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. Product candidates used in late-stage clinical trials must be manufactured in accordance with cGMP requirements and manufacturing specifications and processes must satisfy FDA or other authorities' requirements before any product is approved and before we can manufacture commercial products. Our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of TP-03 to assess compliance with applicable regulations. Our failure, or the failure of our third-party providers and supply chain providers, to comply with such statutory and regulatory requirements could subject us to possible legal or regulatory action, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production, warning letters, the seizure or recall of products, operating restrictions and criminal prosecutions. Any of these actions could have a material impact on clinical supplies of TP-03 or our other product candidates. Contract manufacturers at times encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

#### **Competition**

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, significant competition and an emphasis on intellectual property. We face potential competition from many different sources, including major and specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing approaches and new therapies that may become available in the future. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, combinability, safety profile, convenience, cost, level of promotional activity devoted to them and intellectual property protection.

While there are no currently available on-label prescription pharmaceutical treatments available for the treatment of blepharitis or Demodex blepharitis specifically, a number of other treatments are currently available for the treatment of blepharitis in the U.S. Current treatments for blepharitis in the U.S. include over the counter and off-label remedies such as tea tree oil, lid wipes and artificial tears. We are aware of other companies developing prescription therapies for blepharitis, including Azura Ophthalmics, Aperta Biosciences, LLC, Formosa Pharmaceuticals, Inc., Glaukos Corp., Hovione Scientia, Nicox SA, Premark Pharma, Quorum Innovations and Viatris. To our knowledge, Azura Ophthalmics, Aperta Biosciences, LLC and Glaukos Corp. are the only companies currently focused on Demodex blepharitis and Nicox SA and Premark Pharma are the only companies with blepharitis programs that have completed Phase 2 trials.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

#### **Sales and Marketing**

If TP-03 receives marketing approval, we plan to commercialize TP-03 in the U.S. by developing our own sales organization targeting a subset of the approximately 15,000 prescribing ECPs in the U.S. Throughout our commercialization efforts, we have commenced and intend to further educate ECPs on Demodex blepharitis and how to properly diagnose it by having patients look down during a standard slit lamp examination. Given the importance of increasing awareness and educating patients with blepharitis, we have deployed focused social and digital marketing campaigns for TP-03. During 2022, we began the expansion of our commercial organization to support our business growth and the commercial leadership needed for TP-03 commercial launch readiness in the second half of 2023. We expect this commercial expansion to continue with a meaningful ramp during 2023 as part of our TP-03 commercial launch-readiness activities.

Outside the U.S., we intend to further develop commercialization strategies for TP-03, which may include collaborations with other companies. In March 2021, we executed an out-license agreement with LianBio, granting exclusive commercial rights of TP-03 for the treatment of Demodex blepharitis and MGD within the China Territory. The terms of this agreement are further described below within *License Agreements: LianBio Agreement*.

#### **Intellectual Property**

We protect our intellectual property rights and proprietary technology with a combination of patent rights that we own or license in certain fields of use, trademark rights, confidentiality procedures and contractual provisions. We seek not only to protect our intellectual property rights and proprietary technology in select key global markets, but also to supplement our intellectual property portfolio with new filings and applications to enhance such protection and support commercialization of current and future product candidates. To that end, we continue to seek protection for our technological innovations and branding efforts by filing new patent and trademark applications when and where appropriate. In the normal course of business, we intend to pursue, when possible, composition, method of use, dosing and formulation patent protection, as well as manufacturing and drug development processes and technology.

Our patent portfolio includes a combination of issued patents and pending patent applications licensed from third parties, as well as those assigned solely to us based on our ongoing development activities. The patents and applications in our portfolio can be categorized as related to TP-03, TP-04, TP-05 or future pipeline product candidates and alternative technologies. Some of our issued patents and patent applications are exclusively licensed to us in therapeutic fields of use from Elanco. The patents and patent applications owned by or licensed to us worldwide include approximately 40 issued patents and approximately 57 pending patent applications.

We in-license certain of such patents and patent applications from Elanco. These patents and patent applications relate to lotilaner and are issued or pending in, for example, the U.S., Australia, Brazil, Canada, Chile, China, several European territories, India, Japan, South Korea, Mexico, New Zealand, the Russian Federation, South Africa and Taiwan. The licensed-in portfolio includes approximately 38 issued patents and approximately 4 pending patent applications; the issued patents and at least some of the pending patent applications include composition of matter claims. The estimated natural expiration date of the issued in-licensed patents is approximately 2029 with a potential extension until 2032.

Approximately 36 of our owned patents and pending patent applications include treatment and composition of matter claims which relate to our TP-03 product candidate with respect to our lead indication (e.g., isoxazoline parasiticides for the treatment of Demodex blepharitis), as well as other conditions. These pending patent applications include applications in the U.S., Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Mexico, New Zealand, the Russian Federation, and South Africa. We have two granted patents with treatment claims, U.S. Pat. No. 10,835,517 issued on November 17, 2020, and U.S. Pat. No. 11,197,847 issued on December 14, 2021. The estimated natural expiration date of these issued patents are 2038, and if additional patents issue on these pending applications of ours, the estimated natural expiration dates are between approximately 2038 and 2040.

Our continuing research and development activities, technical expertise and contractual arrangements supplement our existing intellectual property protection and help us maintain our competitive position, and we rely on trade secrets to protect our proprietary information and technologies, especially where we do not believe patent protection is appropriate or obtainable, or where such patents would be difficult to enforce. In order to maintain such trade secrets and other proprietary information, we rely in part on confidentiality agreements with our employees, consultants, contractors, outside scientific collaborators and other advisors.

We also protect our brand through trademark rights. We are the registered owner of approximately nine U.S. pending trademark applications. In order to supplement the protection of our brand, we also own at least three registered internet domain name.

#### **License Agreements**

##### ***January 2019 Elanco In-License Agreement for Skin and Eye Diseases or Conditions in Humans***

In January 2019, we entered into an agreement with Elanco granting us an exclusive, worldwide, sublicensable license to certain intellectual property for the development, marketing, and commercialization of lotilaner for the treatment, palliation, prevention or cure of any eye or skin disease or condition in humans (as amended, the "Eye and Derm Elanco Agreement"). We are obligated to use commercially reasonable efforts to develop and commercialize products comprising lotilaner and must achieve certain developmental milestones within specified achievement deadlines. If we fail to meet these obligations, Elanco has the right to terminate the Eye and Derm Elanco Agreement. We utilize the intellectual property licensed

under the Eye and Derm Elanco Agreement in our TP-03 and TP-04 product candidates. We are permitted to have certain third parties manufacture lotilaner for us and, upon Elanco's consent, additional third parties.

We made a \$1.0 million upfront payment at execution of the Eye and Derm Elanco Agreement in January 2019 and also made a required \$1.0 million clinical milestone payment in September 2020, associated with the first two U.S. pivotal trials for the treatment of Demodex blepharitis. We paid an additional \$2.0 million for our second pivotal trial milestone in April 2021, which was recorded in research and development expense in the accompanying Statements of Operations and Comprehensive Loss for the year ended December 31, 2021. The Company made a contractual payment of \$2.5 million to Elanco following the receipt of \$25 million of proceeds from LianBio during the second quarter of 2021. In June 2022, the Company made a contractual prepayment of \$1.5 million that can be applied towards any milestones that become due under the Eye and Derm Elanco Agreement and/or the Company's in-license agreement with Elanco, granting it a worldwide license to certain intellectual property for the development and commercialization of lotilaner for the treatment, palliation, prevention, or cure of "all other" diseases and conditions in humans (i.e., beyond that of the eye or skin), as amended in June 2022 (the "All Human Uses Elanco Agreement"). In December 2022, the Company recognized \$0.4 million of cost of license fees and collaboration revenue in the accompanying Statements of Operations and Comprehensive Loss for the year ended December 31, 2022 upon receipt of \$10 million of cash proceeds from LianBio for the achievement of a clinical development milestone, which was applied against the \$1.5 million prepayment.

In accordance with the terms of the Eye and Derm Elanco Agreement, we are obligated to make further cash payments to Elanco upon our achievement of various clinical milestones up to an aggregate maximum of \$3.0 million and various sales milestones up to an aggregate maximum of \$79.0 million. If we receive payments from sublicensees, we are obligated to pay Elanco a variable percentage beginning in the low double-digits of such proceeds and decreasing after certain milestones are met, except for sublicense revenue generated after achieving regulatory approval for the use of lotilaner to treat or cure any eye or skin disease or condition in humans. We owe Elanco tiered royalties during the royalty term in the mid-to-high single digits on our future net sales and those of our sublicensees. The royalty term for any licensed product in a given country commences on the date of first commercial sale of such licensed product and ends on the latest of (i) expiration of the last-to-expire of the licensed patents which has at least one valid claim, (ii) the expiration of regulatory exclusivity and (iii) ten years after the first commercial sale of such licensed product in such country. The Eye and Derm Elanco Agreement shall expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the applicable royalty term with respect to such licensed product in such country. The achievement deadlines for eye-related diligence milestones range between 18 months after contract execution to six years after contract execution. The achievement deadlines for dermatological diligence milestones range between 24 months after contract execution to nine years after contract execution.

Either party may terminate the Eye and Derm Elanco Agreement upon a material breach by the other party, solely in the country pertaining to such breach, that is not cured within 60 days after receiving written notice thereof. If we fail to comply with our development obligations under the Eye and Derm Elanco Agreement, and fail to remedy such failure or cure such breach within 60 days, Elanco will have the right to terminate the Eye and Derm Elanco Agreement. If we fail to meet any diligence milestones by the achievement deadlines set forth in the Eye and Derm Elanco Agreement for any reason other than those outside of our reasonable control, and such milestones remain unmet for 120 days after Elanco notifies us thereof, Elanco may terminate the Eye and Derm Elanco Agreement. If we fail to meet certain dermatological milestones by the achievement deadlines set forth in the Eye and Derm Elanco Agreement for any reasons other than those outside of our reasonable control, and such milestones remain unmet for 120 days after Elanco notifies us thereof, Elanco may limit our field of use under the Eye and Derm Elanco Agreement to the treatment, palliation, prevention or cure of eye diseases or conditions in humans only. If Elanco terminates the Eye and Derm Elanco Agreement for our failure to achieve a development milestone by the specified achievement deadline, then we must grant Elanco a non-exclusive, sublicenseable, royalty free license to our patents and know-how relating to lotilaner to develop, manufacture and commercialize lotilaner and any licensed products for the treatment, palliation, prevention or cure of any eye or skin disease or condition in humans. Elanco may also terminate the Eye and Derm Elanco Agreement if we, our affiliates or sublicensees initiate proceedings to oppose Elanco's licensed patents and such proceeding is not withdrawn within 30 days of Elanco providing notice to us; provided that Elanco may not terminate the Eye and Derm Elanco Agreement for a challenge by a sublicensee if we terminate the sublicense with such sublicensee within such 30 day period.

Under the terms of the Eye and Derm Elanco Agreement, we granted Elanco a worldwide, sublicenseable, royalty-free, perpetual license to our patents related to lotilaner and the licensed products and to our know-how to research, develop, make and commercialize lotilaner and the licensed products for all applications in non-human animals, agricultural application, seed treatment applications and urban pest applications related to structural, turf, lawns and gardens. We also granted Elanco an exclusive royalty-free, perpetual license to any intellectual property we conceive from our use of lotilaner applications in non-human animals, agricultural applications, seed treatment applications and urban pest applications related to structural, turf, lawns and gardens.

Elanco retains the sole responsibility to prosecute the patents they license to us and has the first right to enforce the licensed intellectual property against third parties in the licensed field of use but cannot settle or dispose of any such action without our written consent.

**September 2020 Elanco In-License Agreement for All Other Diseases or Conditions in Humans**

In September 2020, we entered into an agreement with Elanco granting us an exclusive, worldwide, sublicensable license to certain intellectual property for the development, marketing, and commercialization of lotilaner for all applications in humans other than the treatment, palliation, prevention or cure of any eye or skin disease or condition (the "All Human Uses Elanco Agreement"). We are obligated to use commercially reasonable efforts to develop and commercialize products comprising lotilaner and must achieve certain developmental milestones within specified achievement deadlines. If we fail to meet these obligations, Elanco has the right to terminate the All Human Uses Elanco Agreement. We utilize the intellectual property licensed under the All Human Uses Elanco Agreement in our TP-05 product candidates. We are permitted to have certain third parties manufacture lotilaner for us and, upon Elanco's consent, additional third parties.

Under the terms of the All Human Uses Elanco Agreement, we issued 222,460 shares of common stock to Elanco at the execution of the September 2020 Agreement, with an estimated fair value of \$3.1 million (\$14.0003 per share, approximating the issuance price of our Series C preferred stock in September 2020).

We are required to make additional cash payments to Elanco upon the achievement of various clinical milestones for an aggregate maximum of \$4.0 million and various commercial and sales threshold milestones for an aggregate maximum of \$77.0 million. In addition, we are obligated to pay contractual royalties to Elanco for sales in certain countries. If we receive payments from sublicensees, we are obligated to pay Elanco a variable percentage beginning in the low double-digits of such proceeds and decreasing after certain milestones are met, except for sublicense revenue generated after achieving regulatory approval for the use of lotilaner to applications in humans other than to treat or cure any eye or skin disease or condition. We owe Elanco tiered royalties during the royalty term in the mid-to-high single digits on our future net sales and those of our sublicensees. The royalty term for any licensed product in a given country commences on the date of first commercial sale of such licensed product and ends on the latest of (a) expiration of the last-to-expire of the licensed patents which has at least one valid claim, (b) the expiration of regulatory exclusivity, and (c) ten years after the first commercial sale of such licensed product in such country. The All Human Uses Elanco Agreement shall expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the applicable royalty term with respect to such licensed product in such country. The achievement deadlines for diligence milestones range between 24 months after contract execution to six years after contract execution.

In March 2021, the Company issued 187,500 shares of its common stock to Elanco to maintain the All Human Uses Elanco Agreement. These issued shares were valued at \$5.5 million, based on our closing stock price of \$29.30 per share on the date this issuance became contractually required and is reported within research and development expense on the accompanying Statements of Operations and Comprehensive Loss for the year ended December 31, 2021. In December 2022, we achieved a clinical milestone related to the initiation of our Phase 2a clinical trial for TP-05 which triggered the recognition of \$0.5 million of research and development expense on the accompanying Statements of Operations and Comprehensive Loss for the year ended December 31, 2022, which partially offset the \$1.5 million prepayment made to Elanco.

Either party may terminate the All Human Uses Elanco Agreement upon a material breach by the other party, solely in the country pertaining to such breach, that is not cured within 60 days after receiving written notice from the other party. If we fail to comply with our development obligations under the All Human Uses Elanco Agreement, and fail to remedy such failure or cure such breach within 60 days, Elanco will have the right to terminate the All Human Uses Elanco Agreement. If we fail to meet any diligence milestones by the achievement deadlines set forth in the All Human Uses Elanco Agreement for any reason other than those outside of our reasonable control, and such milestones remain unmet for 120 days after Elanco notifies us of the failure to meet such diligence milestone, Elanco may terminate the All Human Uses Elanco Agreement. If Elanco terminates the All Human Uses Elanco Agreement for our failure to achieve a development milestone by the specified achievement deadline, then we must grant Elanco a non-exclusive, sublicensable, royalty free license to our patents and know-how relating to lotilaner to develop, manufacture and commercialize lotilaner and any licensed products for all applications in humans other than the treatment, palliation, prevention or cure of any eye or skin disease or condition. Elanco may also terminate the All Human Uses Elanco Agreement if we, our affiliates or sublicensees initiate proceedings to oppose Elanco's licensed patents and such proceeding is not withdrawn within 30 days of Elanco providing notice to us; provided that Elanco may not terminate the All Human Uses Elanco Agreement for a challenge by a sublicensee if we terminate the sublicense with such sublicensee within such 30 day period.

Under the terms of the All Human Uses Elanco Agreement, we grant to Elanco a non-exclusive worldwide, sublicensable, royalty-free, perpetual license to our patents related to lotilaner and the licensed products and to our know-how to research, develop, make and commercialize lotilaner and the licensed products for all applications in non-human animals, agricultural applications, seed treatment applications and urban pest applications related to structural, turf, lawns and gardens.

We also grant to Elanco an exclusive, royalty-free, perpetual license to any intellectual property we conceive from our use of lotilaner for all applications in non-human animals, agricultural applications, seed treatment applications and urban pest applications related to structural, turf, lawns and gardens.

Elanco retains the sole responsibility to prosecute the patents they license to us and has the first right to enforce the licensed intellectual property against third parties in the licensed field of use but cannot settle or dispose of any such action without our written consent.

#### **LianBio Agreement**

On March 26, 2021, we entered into a development and license agreement (the "China Out-License") with LianBio for its exclusive development and commercialization rights of TP-03 (lotilaner ophthalmic solution, 0.25%) in the China Territory for the treatment of Demodex blepharitis and MGD.

Through December 31, 2022, we received payments from LianBio totaling \$80.0 million comprised of initial consideration of \$15.0 million and \$65.0 million for the achievement of specified milestone events.

We will be eligible to receive further consideration from LianBio upon the achievement of additional TP-03 events, including: (i) additional development milestone payments of up to an aggregate of \$25.0 million (includes \$2.5 million for a milestone triggered in February 2023), (ii) China-based TP-03 sales threshold milestone payments of up to an aggregate of \$100.0 million, (iii) tiered low-to-high-teen royalties for the China Territory TP-03 product sales, and (iv) vesting of a LianBio equity warrant upon certain regulatory milestones. The term of the China Out-License will expire upon the expiration of the royalty term in the China Territory, as defined in the agreement, unless earlier terminated. LianBio may also terminate the China Out-License for any reason upon ninety days' prior notice to us.

#### **Government Regulation**

Government authorities in the U.S. at the federal, state and local level and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products such as those we are developing. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. We 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 trials or seek approval of our product candidates. The processes for obtaining regulatory approvals in the U.S. and other countries, as appropriate, along with subsequent compliance with appropriate federal, state, local and foreign statutes and regulations, require the expenditure of substantial time and resources.

#### **U.S. Drug Regulation**

In the U.S., we are subject to extensive regulation by the FDA, which regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and its implementing regulations. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the U.S. Drugs also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. or foreign requirements at any time during the product development process, approval process or post-marketing may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, market acceptance of our products, and our reputation.

Our product candidates are considered small molecule drugs and must be approved by the FDA through the NDA process before they may be legally marketed in the U.S. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice ("GLP") requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin in the U.S. and must be updated annually or when significant changes are made;

- approval by an independent IRB or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, GCP, requirements and other clinical trial-related regulations to establish substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to accept the submission for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements, and of selected clinical investigational sites to assess compliance with GCP;
- potential FDA audit of the preclinical study and/or clinical trial sites that generated the data in support of the NDA filing;
- payment of user fees for FDA review of the NDA;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the U.S.; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Migration Strategy ("REMS") and the potential requirement to conduct post-approval studies.

The data required to support an NDA are generated in two distinct developmental stages: preclinical and clinical. The preclinical and clinical testing and approval process can take many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or condition being treated.

#### ***Preclinical Studies and IND Submission***

Before testing any drug product candidate in humans, the product candidate must undergo rigorous preclinical testing. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for certain safety/toxicology studies. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin in the U.S.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA and clinical trials may proceed under such IND at such time, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development along with any subsequent changes to the investigational plan.

#### ***Clinical Trials***

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries, including the website maintained by the U.S. National Institutes of Health, ClinicalTrials.gov.



A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may still submit data from the clinical trial to the FDA in support of an NDA. The FDA may agree to accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements and the FDA is able to validate the data through an onsite inspection, if deemed necessary, and the practice of medicine in the foreign country is consistent with the U.S.

Clinical trials in the U.S. generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- Phase 2 clinical trials generally involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the safety and effectiveness of the product for its intended use and to establish the overall benefit/risk relationship of the product to provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.
- A Phase 1/2 clinical trial has elements of a Phase 1 trial and a Phase 2 trial. We have designated our TP-04 and TP-05 trials as Phase 1/2 trials since we intend to go beyond the typical safety and tolerability assessments of a Phase 1 trial and intend to have these trials include additional efficacy assessments as well.
- A Phase 2b/3 clinical trial has elements of a late Phase 2 trial and a Phase 3 trial. We have designated Saturn-1 as a Phase 2b/3 trial as it is both our first multi-center trial based in the U.S., and also a pivotal trial for the U.S.

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

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate 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.

Equivalent, and similarly detailed, obligations will apply to the conduct of clinical trials in third countries including the European Union ("EU").

#### ***NDA Review and Marketing Approval***

Following completion of clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry and manufacturing information, and other information in a request for approval to market the drug for one or more specified indications. The application must include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-



sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA must be obtained before a drug may be marketed in the U.S.

Under the PDUFA, as amended, each NDA must be accompanied by an application user fee. FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a qualifying small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product NDA also includes a non-orphan indication.

The FDA conducts a preliminary review of all submitted NDAs before it accepts them for filing to determine if they are sufficiently complete to permit a substantive review, and the FDA may request additional information rather than accepting the NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

Under PDUFA, the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, standard review and priority review. According to PDUFA performance goals, the FDA endeavors to review applications subject to standard review within ten months, whereas the FDA's goal is to review priority review applications within six months, depending on whether the drug is a new molecular entity. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

In addition, under the Pediatric Research Equity Act of 2003 as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may also audit data from clinical trials to ensure compliance with GCP requirements.

The FDA generally accepts data from foreign clinical trials in support of an NDA if the trials were conducted under an IND. If a foreign clinical trial is not conducted under an IND, the FDA nevertheless may accept the data in support of an NDA if the study was conducted in accordance with GCP requirements and the FDA is able to validate the data through an on-site inspection, if deemed necessary. Although the FDA generally requests that marketing applications be supported by some data from domestic clinical studies, the FDA may accept foreign data as the sole basis for marketing approval if (1) the foreign data are applicable to the U.S. population and U.S. medical practice, (2) the studies were performed by clinical investigators with recognized competence, and (3) the data may be considered valid without the need for an on-site inspection or, if the FDA considers the inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA also closely analyzes the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications and potentially subject to other requirements. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, including

the potential requirement to conduct additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, or to conduct additional preclinical studies or manufacturing changes. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

#### **Post-Approval Requirements**

Following approval of a new product, the product is subject to continuing regulation by the FDA, including, among other things, requirements relating to facility registration and drug listing monitoring and record keeping, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with 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 user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. The FDA strictly regulates marketing, labeling, advertising and promotion of drugs, including after they are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS"), to assure the safe use of the product. If the FDA concludes that a REMS is needed, the NDA sponsor must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, its manufacturer or the NDA holder, including recalls.

The FDA may withdraw approval of a product if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Corrective action could delay drug distribution and require significant time and financial expenditures. 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, suspension of the approval, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

### **Other Regulatory Matters**

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. For example, in the U.S., sales, marketing and scientific and educational programs also must comply with state and federal fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws. These laws include the following:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of an item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal civil False Claims Act, which imposes civil penalties, sometimes pursued through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent or making a false statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act ("HIPAA"), which imposes criminal liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA and its implementing regulations, also imposes obligations, on certain covered entity health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices, including off-label or pre-approval promotion;
- the federal Physician Payments Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to Centers for Medicare & Medicaid Services ("CMS") information regarding direct or indirect payments and other transfers of value to physicians and teaching hospitals (and certain other practitioners as of 2022), as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers, state laws that require pharmaceutical manufacturers to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, state laws that require pharmaceutical manufacturers to report information on the pricing of certain drug products, state and local laws that require the licensure and registration of pharmaceutical sales representatives, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Furthermore, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California has enacted the California Consumer Privacy Act ("CCPA"). The CCPA created new transparency requirements, granted California consumers (as that word is broadly defined in the law)

several new rights with regard their personal information, and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. In addition, in November 2020, California voters approved the California Privacy Rights Act ("CPRA") ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency ("CPPA"). The amendments introduced by the CPRA went into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or potential statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and potential damages. The CCPA could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information. We have implemented processes to manage compliance with the CCPA and we continue to assess the impact of the CPRA, and other state legislation, on our business as additional information and guidance becomes available.

Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, compliance oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

#### ***U.S. Patent-Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office ("USPTO"), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA") or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full 505(b)(1) NDA.

However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

#### **European Union Drug Development**

Similar to the U.S., the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the European Union Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the regime of the Clinical Trials Directive, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority ("NCA"), and one or more ethics committees. Under the regime of the Clinical Trials Directive all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

In order to streamline the regulation of clinical trials across the EU, the EU legislator has adopted Regulation (EU) No 536/2014, or the EU Clinical Trials Regulation. The new EU Clinical Trials Regulation, which repeals and replaces the EU Clinical Trials Directive, introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU. The main characteristics of the regulation include: a streamlined application procedure through 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. The EU Clinical Trials Regulation is applicable as of January 31, 2022 and is applicable directly in all countries of the EEA (which is comprised of 27 Member States of the EU plus Norway, Iceland and Liechtenstein). Clinical trials authorized under the current Clinical Trials Directive before January 31, 2023 can continue to be conducted under the Clinical Trials Directive until January 31, 2025. An application to transition ongoing trials from the current Clinical Trials Directive to the new Clinical Trials Regulation will need to be submitted and authorized in time before the end of the transitional period. The new Clinical Trials Regulation is intended to simplify and streamline the approval of clinical trials in the EEA.

#### **European Union Drug Review and Approval**

In order to market any product outside of the U.S., a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy, and governing, among other things, clinical trials, marketing authorization, commercial sales, and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trial or marketing of the product in those countries or jurisdictions.

##### *Marketing Authorization*

In the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are a number of types of marketing authorizations.

- The Community MA is adopted by the European Commission in the form of a decision through the Centralized Procedure. The decision, which is based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP") of the EMA, is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional, on approval by the EMA for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

Under the Centralized Procedure, the CHMP established at the EMA is responsible for conducting an initial scientific assessment of a product. The maximum timeframe for the evaluation of an MA under the Centralized Procedure 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 evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP

accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the Centralized Procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

- MAs based on the Mutual Recognition Procedure or the Decentralized Procedure are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product is first authorized by a Reference Member State this may be recognized by other Concerned Member States through the Mutual Recognition Procedure. Alternatively, a product can be approved simultaneously in various EU Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the EU Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State. The competent authority of the Reference Member State prepares a draft assessment report, a draft Summary of Product Characteristics ("SmPC") and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the "Concerned Member States") for their approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling or packaging proposed by the Reference Member State, the product is subsequently granted a national MA in all the Member States (i.e., in the Reference Member State and the Concerned Member States).

#### Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payers, such as government health programs, commercial insurance, and managed healthcare organizations. In the U.S., for example, principal decisions about reimbursement for new products are typically made by CMS or by Medicare's contractors and third-party payers or insurance plans. These entities decide whether and to what extent a new product will be covered and reimbursed based on clinical needs and economic impact. To date no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payer-by-payer basis.

Increasingly, third-party payers are requiring that drug companies provide them with discounts usually in the form of rebates from list prices and are challenging the prices charged for medical products. Further, such payers are examining the medical necessity and reviewing the cost effectiveness of newly launched drugs. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs as several large payers have implemented new market blocks that can last anywhere between six to twelve months. Third-party payers may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products, with no assurance that coverage and adequate reimbursement will be obtained.

If we successfully commercialize any of our product candidates, we may participate in the Medicaid Drug Rebate Program. Participation is required for federal funds to be available for our covered outpatient drugs under Medicaid and, if applicable, Medicare Part D. Under the Medicaid Drug Rebate Program, we would be required to pay a mandatory rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and, if applicable, Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part D. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B ceiling price for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the U.S. Department of Veterans Affairs ("VA") Federal Supply Schedule ("FSS") pricing program. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, the VA, U.S. Department of Defense ("DoD"), Public Health Service and U.S. Coast Guard - that is no higher than the statutory Federal Ceiling Price ("FCP"). Manufacturers also are obligated to calculate and submit to the VA on a quarterly and annual basis, their Non-Federal Average Manufacturer Price ("Non-FAMP"), which the VA uses to calculate the FCP. Moreover, pursuant to regulations issued by the DoD Defense Health Agency to implement

Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies.

The requirements under the Medicaid, 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results. If we fail to comply with any applicable obligations under governmental pricing programs that we participate in, we could be subject to additional reimbursement requirements, significant civil monetary penalties, sanctions and fines, and those could negatively impact our business, financial condition, results of operations and growth prospects.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing.

#### **Healthcare Reform**

The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, in March 2010, the Affordable Care Act was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Affordable Care Act made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate. The Affordable Care Act also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits.

There have been judicial challenges to certain aspects of the Affordable Care Act, as well as efforts by Congress to modify, and by agencies to alter the implementation of, certain aspects of the Affordable Care Act. For example, Congress eliminated, starting January 1, 2019, the tax penalty for not complying with the Affordable Care Act's individual mandate to carry health insurance. Further, the Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D to close the coverage gap in most Medicare drug plans, commonly referred to as the donut hole.

It is possible that the ACA, as currently enacted or may be amended in the future, as well as other healthcare reform measures including those that may be adopted in the future, may result in more rigorous coverage criteria, and less favorable payment methodologies, or other downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement or restriction on coverage under Medicare or other government programs may result in a similar reduction or restriction by private payers.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012 ("ATRA"). Subsequent legislation extended the 2% reduction, generally to 2031. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. ATRA, among other things, also reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Other new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.



Additionally, there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state 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 drug products. At the state level, legislatures have increasingly passed legislation and implemented 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.

Moreover, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payers often follow Medicare coverage policy and payment limitations in setting their own payment rates and in establishing their formulary placement.

Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law. The IRA introduces several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs and a change in manufacturer liability under the program which could negatively affect the profitability of our product candidates. The IRA sunsets the current Part D coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA establishes a Medicare Part B inflation rebate scheme effective January 2023 and a Medicare Part D inflation rebate scheme effective October 2022, under which, generally speaking, manufacturers will owe rebates if the price of a Part B or Part D drug increases faster than the pace of inflation. Failure to timely pay a Part B or D inflation rebate is subject to a civil monetary penalty. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologics without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. Congress continues to examine various policy proposals that may result in pressure on the prices of prescription drugs with respect to the government health benefit programs and otherwise. The IRA or other legislative changes could impact the market conditions for our product candidates.

## **Human Capital Resources**

### *Human Capital*

As of December 31, 2022, we had 87 employees, all of which were full-time employees. None of our employees are represented by a labor union or covered under a collective bargaining agreement.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

### *Employee Development and Training*

Our values-based culture and our employees are a critical component of our success. We strive to create a supportive and professional environment for our employees. We expend considerable management time and attention, and financial resources, to attracting, retaining, and motivating exceptional individuals at our company.

### *Diversity, Equity, and Inclusion*



We are committed to creating and maintaining a workplace free from discrimination or harassment on the basis of race, color, citizenship, religion, creed, national origin, ancestry, gender, sexual orientation, age, marital status, veteran status, disability, medical condition, or any other status protected by applicable law. Our employment policies and compliance trainings prohibit such discrimination and harassment. Our management team and employees are also expected to exhibit and promote honest, ethical, and respectful conduct in the workplace. All of our employees must adhere to a code of business conduct and ethics that sets standards for appropriate behavior and are required to attend annual training on the code of business conduct and ethics.

#### **Corporate Information**

We were incorporated under the laws of the State of Delaware in November 2016. Our principal executive offices are located at 15440 Laguna Canyon Road, Suite 160, Irvine, California 92618. Our telephone number is (949) 409-9820. Our website address is [www.tarsusrx.com](http://www.tarsusrx.com). Information contained on the website is not incorporated by reference into this Annual Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

#### **Facilities**

We currently lease approximately 27,807 square feet of office and laboratory space in Irvine, California under certain leases that last expire in January 2024, with a renewal option for a term of three years. We believe that this space will be sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms.

#### **Legal Proceedings**

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

#### **Item 1A. Risk Factors**

*Investing in our common stock is speculative and involves a high degree of risk. Before investing in our common stock, you should consider carefully the risks described below, together with the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes appearing at the end of this Annual Report on Form 10-K. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "Special Note Regarding Forward-Looking Statements."*

#### **Risks Related to our Business and Operations**

***We currently generate no revenues from sales of any products and may never generate revenue or be profitable.***

We have no products approved for commercial sale and do not anticipate generating any product revenue, unless and until either TP-03 or another product candidate receives the regulatory approvals necessary for commercialization in one or more jurisdictions. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any future collaborator's ability, to achieve a number of challenging objectives, including:

- timely receipt of regulatory approvals from applicable regulatory authorities for TP-03 or any other product candidates for which we successfully complete clinical development;
- successful and timely completion of preclinical and clinical development of our product candidates;
- successfully educating ECPs about Demodex blepharitis and related diagnosis;

- successful commercial launch following any regulatory approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- commercial acceptance of TP-03 and any of our other product candidates by patients, the medical community and third-party payers;
- establishing and maintaining relationships with contract research organizations ("CROs") and clinical sites for the clinical development, both in the U.S. and internationally, of our product candidates;
- making any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved;
- obtaining an IND prior to commencing clinical trials in the U.S. for a particular indication, such as TP-04 for the potential treatment of rosacea (although for TP-04 we first intend to conduct a Phase 1/2 trial outside the U.S. and thus do not plan to submit an IND prior to this trial) and TP-05 for potential Lyme disease prophylaxis and community malaria reduction;
- a continued acceptable safety and efficacy profile both prior to and following any marketing approval of our product candidates;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- obtaining favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our existing or acquired product candidates;
- obtaining coverage and adequate reimbursement for customers and patients from government and third-party payers for product candidates that we develop;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, retain key employees and continue our operations.

***We expect to expand our development, regulatory and operational 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 we advance our research and development programs and commercialization efforts, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, quality, regulatory affairs, manufacturing and quality control and, if TP-03 or any of our other product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and execution of clinical trials for our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities. If we do not effectively manage the expansion of our operations, we could experience weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations also could lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third-party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacture of our product candidates. We cannot assure you that the services of such third-party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.***

We are highly dependent on the expertise of our executive officers, as well as the other members of our scientific and clinical teams and certain advisors to develop and soundly execute our business strategy. Although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain key person insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for TP-03 or other product candidates, sales and marketing personnel, are 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 for and commercialize our product candidates. Competition to hire qualified personnel in our industry 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.

Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical 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 be employed by employers other than us and 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, and our business, prospects, financial condition and results of operations may be adversely affected.

Many of our employees have become or will become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

***Our internal information technology systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.***

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, interruptions or cyber incidents resulting from the conflict between Russia and Ukraine, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including 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), which may compromise our system infrastructure or lead to data leakage. Further, due to the political uncertainty involving Russia and Ukraine, there is an increased likelihood that escalation of tensions could result in cyber attacks that could either directly or indirectly impact our operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our drug candidates could be delayed.

While we have not experienced any such system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, including private lawsuits or class actions under the California Consumer Privacy Act, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

***Product liability lawsuits against us could cause us to incur substantial liabilities, could divert our resources and could limit or delay our commercialization of any product candidates that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. While we currently have no products that have been approved for commercial sale, the use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the

product, healthcare providers, pharmaceutical companies or others selling such products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- delay, variation or termination of clinical trials;
- decreased demand for any product candidates or products that we may develop;
- withdrawal of regulatory approval, recall, restriction on the approval or a black box warning or contraindication for an approved drug;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;
- substantial monetary awards to study subjects or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability or delay of our efforts to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as our product candidates advance through clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive, thus 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 a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

***Our employees, independent contractors, including our CROs and CMOs, commercial partners, consultants, suppliers, service providers, and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.***

We are exposed to the risk that our employees, independent contractors, including our CROs and CMOs, commercial partners, consultants, suppliers, service providers, and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar foreign regulatory authorities, including those laws that require the reporting of true, complete, and accurate information to such foreign regulatory authorities; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete, and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our nonclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, and the precautions we take to detect and prevent this activity 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 or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, imprisonment, other sanctions, contractual damages, reputational harm, future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***The COVID-19 pandemic, which began in late 2019 and has spread worldwide, may continue to affect our ability to initiate and complete preclinical studies and clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business and operations.***

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain.

Our business, operations and clinical development timelines and plans have been and could continue to be adversely affected by COVID-19, and could be adversely impacted by other health epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of CROs upon whom we rely. The COVID-19 pandemic has affected multiple countries worldwide, including those where we have planned and ongoing preclinical studies and clinical trials. In addition, in response to the COVID-19 pandemic, many state, local and foreign governments put in place quarantines, executive orders, shelter-in-place orders and similar government orders and restrictions in order to control the spread of the disease. Such orders or restrictions, and the perception that such orders or restrictions could continue or, after being lifted, be reinstated for a period of time, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects that could negatively impact productivity and disrupt our business and operations. While some of the orders and restrictions have been lifted, we cannot be certain that such orders and restrictions will not be reinstated in the future. We have implemented a vaccination policy for our employees and have also implemented enhanced travel-safe policies for our employees' travel to our clinical sites. We may take further actions that alter our operations as may be required by federal, state or local authorities, or which we determine are in the best interests of our employees.

Moreover, our clinical development timelines and plans could be affected by the COVID-19 pandemic as we and the third-party manufacturers and clinical research organizations that we engage may face disruptions. Site initiation and patient enrollment could be delayed or suspended due to prioritization of hospital resources toward the COVID-19 pandemic or patients not having a desire to enroll in clinical trials due to concerns regarding COVID-19. While we have not experienced any material delays in enrollment, we cannot be certain that we will not experience future delays in enrollment. In addition, some patients may not be able to comply with clinical trial protocols and the ability to conduct follow up visits with treated patients may be limited if patients do not want to participate in follow up visits due to concerns regarding COVID-19 or if quarantines impede patient movement or interrupt healthcare services. There may be shortages in the raw materials used in the manufacturing of our product candidates or laboratory supplies for our preclinical studies and clinical trials, in each case, because of ongoing efforts to address the outbreak.

We cannot assure that the inability to collect such clinical data would not have an adverse impact on our clinical trial results. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 could be adversely impacted.

We may experience disruptions that could severely impact our business, preclinical studies, and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials, including receiving any required "IND";
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- manufacturing disruptions;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- delays in the transport of clinical trial materials;

- changes in local regulations as part of a response to the COVID-19 coronavirus pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- difficulties recruiting or retaining patients for our planned clinical trials if patients are affected by the virus or are fearful of visiting or traveling to clinical trial sites because of the outbreak;
- interruption of or changes in key clinical trial activities, such as clinical trial site monitoring, implementation of virtual monitoring, use of local testing labs, or home delivery of study drugs, due to limitations on travel imposed or recommended by federal or state governments, employers and others, use of new digital technologies for subject visits or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays in the operations of the FDA which may impact review and approval timelines;
- delays in regulatory approvals for our product candidates due to the FDA focusing on clinical trials related to therapies and vaccines targeting COVID-19;
- refusal of the FDA to accept data, including from clinical trials in affected geographies or failure to comply with updated FDA guidance and expectations related to the conduct of clinical trials during the COVID-19 pandemic; and
- interruption or delays to our sourced discovery and clinical activities.

The response to the COVID-19 pandemic may redirect resources with respect to regulatory matters in a way that would adversely impact our ability to pursue marketing approvals. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions. Furthermore, third parties, including manufacturers, medical institutions, clinical investigators, CROs and consultants with whom we conduct business, are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties continue to experience shutdowns or business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

The extent to which the COVID-19 pandemic impacts our business, clinical trials, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration of the pandemic, its severity, the actions to contain the virus or address its impact, and how quickly and to what extent government orders and mandates are lifted and normal economic and operating activities can resume. Further, while the potential economic impact brought by and the duration of COVID-19 may be difficult to assess or predict, the COVID-19 pandemic has resulted in significant disruptions of global financial markets, which could reduce our ability to access capital, which could in the future negatively affect our liquidity. To the extent the COVID-19 pandemic adversely affects our business, clinical trials, results of operations and financial condition, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change.



***We or the third parties upon whom we depend on may be adversely affected by earthquakes, fires or other natural disasters, or geopolitical events and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Any unplanned event, such as earthquakes, fires, flood, explosion, extreme weather, medical epidemic, pandemics, power outages, telecommunication failures, war or other military conflict, terrorist activities or other natural or manmade accidents or incidents could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

***Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.***

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The economic downturn resulting from the COVID-19 pandemic precipitated a global recession, and together with high rates of inflation and energy supply issues experienced in certain regions, have led to regional and/or global macroeconomic challenges, the effects of which may be of an extended duration. In particular, acute rising energy costs may further adversely affect productivity and economic conditions in Europe. Additionally, financial pressures may cause government or other third-party payers to more aggressively seek cost containment measures in healthcare and other settings. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships (including inflation) may also affect patients' ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, business and results of operations. The current inflationary environment related to increased aggregate demand, supply chain constraints and the effects from the armed conflict in Ukraine (including the effects of the sanctions that were implemented in response to the conflict and the resulting impacts on the commodity market and supply chains) have also increased our operating expenses and may continue to affect our operating expenses. Our operational costs, including the cost of energy, materials, labor, distribution and our other operational and facilities costs are subject to market conditions and are being adversely affected by inflationary pressures. Economic conditions may also adversely affect the ability of our distributors, customers and suppliers to obtain the liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on our product sales, business and results of operations. A significant worsening of global economic conditions could precipitate or materially amplify the other risks described herein.

We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our accompanying Balance Sheets. The global spread of COVID-19 has also led to disruption and volatility in the global capital markets. The value of our investments may also be adversely affected by interest rate fluctuations, inflation, downgrades in credit ratings, illiquidity in the capital markets and other factors that may result in other-than-temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments.

#### **Risks Related to our Financial Position and Need for Additional Capital**

***We have incurred significant losses and negative cash flows from operations since our inception and anticipate that we will continue to incur significant expenses and losses for the foreseeable future.***

We do not have any products approved for sale, we have not generated any revenue from sales of our products and have incurred net losses each year since our company's formation in 2016. We have funded our operations primarily from the sale and issuance of redeemable convertible preferred stock, convertible promissory notes and the sale of our common stock in our initial public offering ("IPO") and in a subsequent follow-on offering in May 2022 (the "Follow-On Public Offering"), as well as proceeds from our China Out-License and draws on our Credit Facility (defined below). For the years ended December 31, 2022 and 2021, our net losses were \$62.1 million and \$13.8 million, respectively. As of December 31, 2022 and December 31, 2021, we had an accumulated deficit of \$108.8 million and \$46.7 million, respectively. Additionally, the net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indicator of our future performance. The size of our future net losses will depend, in part, on the

rate of future growth of our expenses and our ability to generate revenue. We expect that it will be over a year or more, if ever, before we have a product candidate ready for commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance and commercialize, if approved, our product candidates. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our accumulated deficit and working capital.

We expect to continue incurring significant expenses and increasing operating losses for the foreseeable future. We expect that our expenses will increase substantially if and as we:

- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval, including TP-03 for the potential treatment for Demodex blepharitis;
- enhance our product development and planned future commercialization efforts, including through hiring additional clinical, regulatory, quality control and scientific personnel;
- seek marketing approvals and reimbursement for our product candidates;
- prepare for and initiate additional preclinical, clinical and other studies for our product candidates;
- change or add additional manufacturers or suppliers, some of which may require additional permits or other governmental approvals;
- create additional infrastructure to support our operations as a public company, including adding operational, financial and management information systems and personnel;
- seek to identify, assess, acquire or develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments in connection with the development or approval of our product candidates;
- maintain, protect, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase beyond our expectations if, among other things:

- there are any delays in establishing appropriate manufacturing arrangements for or completing the development of any of our product candidates;
- we are required by regulatory authorities to perform clinical trials or studies in addition to, or different than, those that we currently expect; or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain regulatory approval for and are successful in commercializing one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

***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 activities in 2016. Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing our company, raising capital, identifying and developing product candidates, establishing licensing arrangements and/or acquiring necessary

technology, undertaking research, preclinical studies and clinical trials of our product candidates, establishing arrangements for the manufacture of product candidates and longer-term planning for potential commercialization of our product candidates, including TP-03 for the potential treatment of Demodex blepharitis. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have limited experience in and have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product 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 or a history of successfully developing, obtaining marketing approval for and commercializing products. In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We will need to transition 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 may need to obtain additional funding to complete the development and any commercialization of our product candidates, if approved. If we are unable to raise this necessary capital when needed, we would be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.***

Since our inception, we have funded our operations through private placements of preferred stock, convertible promissory notes, the sale of our common stock in our IPO and our Follow-On Public Offering, as well as proceeds from our China Out-License and draws on our Credit Facility. Over the next few years, we expect our expenses to increase substantially and we will require a larger amount of capital to fund the development of our product candidates. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Furthermore, as a public company, we incur significant legal, accounting and other costs associated with operating as a public company.

We believe that our cash, cash equivalents and marketable securities of \$217.0 million as of December 31, 2022 is sufficient to fund our current and planned operations for at least the next twelve months from the date of filing this Annual Report on Form 10-K. These funds together with the \$5.0 million of expected proceeds from the China Out-License during 2023, and available funds under our Credit Facility, will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2026. Further, we believe our existing cash, cash equivalents and marketable securities will be insufficient for us to concurrently fund the commercialization of TP-03, if approved, for the potential treatment of Demodex blepharitis and continue to develop our other product candidates.

We will need to raise substantial additional capital to complete the development and commercialization of our other product candidates through one or more of: equity offerings, draws from our Credit Facility, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources.

We may need to raise additional funds earlier than currently anticipated if we choose to pursue additional indications for our product candidates, acquire new product candidates or otherwise expand our business more rapidly than we presently planned. We have based these estimates on assumptions that may prove to be incorrect or require adjustment because of our ongoing business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope and costs of manufacturing development and commercial manufacturing activities and our ability to scale them up;
- the scope, rate of progress, costs and results of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost, timing and outcome of regulatory review of our product candidates, including the potential for regulatory authorities to require that we conduct more studies and trials than those that we currently expect to conduct and the costs of post-marketing studies or risk evaluation and mitigation strategies that could be required by regulatory authorities;

- potential changes in the regulatory environment and enforcement rules;
- the cost and timing of establishing sales and marketing capabilities, if any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our ability to satisfy our outstanding debt obligations;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- potential changes in pharmaceutical pricing and reimbursement infrastructure;
- the costs associated with being a public company; and
- the cost associated with commercializing our product candidates, if they receive marketing approval.

Identifying potential product candidates and conducting preclinical studies 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 marketing approval. In addition, our product candidates, if approved, may not achieve adequate product sales or commercial success. We expect to commercialize TP-03 for the treatment of Demodex blepharitis during the second half of 2023, but could experience delays with approval. Accordingly, we will need to continue to sustain our existing capital resources to fund our future operating expenses and capital expenditure requirements. Adequate additional financing may not be available to us on acceptable terms, or at all, and may be impacted by the economic climate and market conditions. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, limit, reduce or eliminate our research and development programs or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of management from day-to-day activities and distract from our research and development efforts. Alternatively, 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.

In February 2022 we executed a loan and security agreement (the "Credit Facility"), as amended in January 2023 (see *Note 10*) with Hercules Capital, Inc. ("Hercules") and Silicon Valley Bank ("SVB"). Concurrent with the execution of the Credit Facility, the Company made a \$20.0 million draw. As of December 31, 2022, the Credit Facility provides for a remaining aggregate principal amount of up to \$135.0 million with tranches availability as follows: \$25.0 million related to the NDA submission for TP-03, \$35.0 million upon FDA approval of TP-03, \$50.0 million upon achievement of product net revenue thresholds, and \$25.0 million upon lender approval. On March 15, 2023 we made a \$5.0 million draw (including SVB's commitment of \$1.25 million) from the \$25.0 million tranche associated with the NDA submission of TP-03. Each of the tranches may be drawn down in \$5.0 million increments at our election. As reported elsewhere, on March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver, and SVB was subsequently transferred into a new entity, Silicon Valley Bridge Bank, N.A. On March 12, 2023, the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception. Such parties also announced, among other items, that Silicon Valley Bridge Bank has assumed the obligations and commitments of former SVB, commitments to advance under existing credit agreements will be honored in accordance with and pursuant to the terms of such credit agreements and any other duties or roles under existing credit agreements will be performed by Silicon Valley Bridge Bank in accordance with and pursuant to the terms of such credit facilities. However there can be no assurances that the closure of SVB, or any other financial institution, or any related impacts across the financial services industry will not adversely affect our ability to access the additional the additional availability under the Credit Facility.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through possible combinations of equity offerings, debt financings, collaborations, strategic alliances and licensing

arrangements. 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 common stockholder. For example, in May 2022, we completed the Follow-On Public Offering, in which received total gross proceeds of \$79.5 million (before underwriting discounts, commissions and other estimated offering expenses) through the issuance of 5.9 million shares of our common stock. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions. For example, the Credit Facility restricts our ability to pursue certain transactions that we may believe to be in our best interests without the prior written consent of Hercules and SVB, including but not limited to, incurring additional indebtedness (subject to certain exceptions with respect to issuing convertible indebtedness), incurring additional liens (including a negative pledge on intellectual property), engaging in mergers, acquisitions and consolidations; conducting asset sales or exclusively licensing our assets in a transaction that constitutes legal transfer to such licensee, making investments and loans, engaging in certain corporate changes, transacting with affiliates, declaring dividends or making other distributions, and making payments on certain other indebtedness.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders, and may cause the market price of our shares to decline. 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 product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business and our financial condition and results of operations.***

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver, and SVB was subsequently transferred into a new entity, Silicon Valley Bridge Bank, N.A. On March 12, 2023, the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception. Such parties also announced, among other items, that Silicon Valley Bridge Bank has assumed the obligations and commitments of former SVB, commitments to advance under existing credit agreements will be honored in accordance with and pursuant to the terms of such credit agreements and any other duties or roles under existing credit agreements will be performed by Silicon Valley Bridge Bank in accordance with and pursuant to the terms of such credit facilities. A similar structure was established for Signature Bank.

We currently maintain cash held in deposit at third-party financial institutions in the U.S., including at SVB. These deposits are insured by the Federal Deposit Insurance Corporation (FDIC) in an amount up to \$250,000 for any depositor (and with respect to SVB are fully insured per recent correspondence from the FDIC), and any cash deposits in excess of this insured amount could be lost. To the extent we hold cash deposits in amounts that exceed the FDIC insurance limitation, in the event of a failure of any of the financial institutions where we maintain deposits, we may incur a loss to the extent such loss exceeds the FDIC insurance limitation, and such a failure could have a material adverse effect upon our liquidity, operations and our results of operations.

Additionally, we and other parties with whom we conduct business may be unable to access funds in such deposit account or other accounts, including money market funds, held with a financial institution or lending arrangements with such a financial institution. Our ability and any of our counter-party's ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from financial institutions in the future and uncertainty remains over liquidity concerns in the broader financial services industry.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to \$25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such

instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

***Our existing indebtedness may limit our flexibility in financing and operating our business and adversely affect our business, financial condition and results of operations.***

In February 2022 we entered into the Credit Facility with Hercules and SVB, as amended on January 5, 2023. As of December 31, 2022, the Credit Facility provides for a remaining aggregate principal amount of up to \$135.0 million with tranching availability. In addition to these amounts, we may borrow substantial funds in the future to provide a portion of the capital needed in our business and may secure the repayment of such borrowings by placing additional liens or other encumbrances on our assets. Our Credit Facility contains customary conditions to borrowing, events of default and affirmative and negative covenants, including covenants that restrict our ability to incur additional indebtedness, incur additional liens, conduct asset sales or exclusively license our assets in a transaction that constitutes legal transfer to such licensee, make investments and loans, engage in certain corporate changes, transact with affiliates, or declare dividends or make other distributions to holders of our stock. Such restrictions could limit our ability to take certain actions and could reduce our flexibility to run and manage our business which could have an adverse effect on our results of operations. The obligations under the Credit Facility are secured by a first priority lien on substantially all of our assets, excluding our intellectual property on which there is a negative pledge, subject to customary exceptions. If we were unable to repay amounts due under the Credit Facility, Hercules and SVB could proceed against such assets. Any declaration by Hercules or SVB of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

***We may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause or to incur debt or assume contingent liabilities, and subject us to other risks.***

In the future, we may enter into transactions to acquire other businesses, products or technologies or enter into strategic partnerships, including licensing. If we do identify suitable acquisition or partnership candidates, we may not be able to make such acquisitions or partnerships on favorable terms, or at all. Any acquisitions or partnerships we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. For example, our Credit Facility may restrict our ability to pursue certain mergers, acquisitions or consolidations without obtaining the prior consent of Hercules and SVB or repaying our outstanding loan amounts.

We could incur losses resulting from undiscovered liabilities of the acquired business or partnership that are not covered by the indemnification we may obtain from the seller or our partner. In addition, we may not be able to successfully integrate any acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions or partnerships may also divert management attention from day-to-day responsibilities, lead to a loss of key personnel, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or partnerships or the effect that any such transactions might have on our operating results.

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

We have incurred substantial losses during our history which we expect to continue, do not expect to become profitable in the near future, and we may never achieve profitability. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards ("NOLs"), and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have not yet completed an ownership change analysis. If a requisite ownership change occurs, the amount of remaining tax attribute carryforwards available to offset taxable income and reduce income tax expense in future years may be restricted or eliminated. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. 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. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

***U.S. federal income tax reform and the implementation of such reforms could adversely affect us.***

On December 22, 2017, the U.S. enacted the "Tax Cuts and Jobs Act" (the "TCJA") that significantly reformed the Code. The TCJA, among other things, includes contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), the limitation of the deduction for NOLs arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits. The financial statements contained herein reflect the effects of the TCJA based on current guidance. However, there remain uncertainties and ambiguities in the application of certain provisions of the TCJA, and, as a result, we made certain judgments and assumptions in the interpretation thereof.

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act ("FFCR Act") was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017 and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. It is also likely that Congress will enact additional tax legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act or the CARES Act.

#### **Risks Related to Development and Commercialization of our Product Candidates**

***We are heavily dependent on the success of our lead product candidate, TP-03, for the treatment of Demodex blepharitis. If we are unable to successfully complete the clinical development program, obtain regulatory approval for, or commercialize, TP-03, or experience significant delays in doing so, our business will be materially harmed.***

We currently have no products that are approved for commercial sale and we have never had any products approved for sale or commercialized. To date, we have invested a substantial majority of our business efforts and financial resources to the preclinical and clinical development of TP-03 for the treatment of Demodex blepharitis. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize TP-03 for the treatment of Demodex blepharitis. While the NDA for TP-03 for the potential treatment of Demodex blepharitis was accepted by the FDA, with a stated PDUFA decision date of August 25, 2023, we cannot accurately predict when or if TP-03 will be proven to be effective or safe in humans or whether it will receive regulatory approval. Before we can generate any revenue from sales of TP-03, we will be required to seek and obtain regulatory approval, secure adequate manufacturing supply to support commercial sales and build a commercial organization. Further, the commercial success of TP-03 will also depend on patent protection, successfully educating ECPs about Demodex blepharitis and related diagnosis, acceptance of TP-03 by patients, the medical community and third-party payers, TP-03's ability to compete with other therapies, secure adequate healthcare coverage and reimbursement, and maintenance of an acceptable safety profile following approval, among other factors. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize TP-03, which would materially harm our business. If we were required to discontinue development of TP-03, or if TP-03 does not receive regulatory approval, fails to achieve significant market acceptance, or fails to receive adequate reimbursement, we would be delayed by many years in our ability to achieve profitability, if ever, and may not be able to generate sufficient revenue to continue our business.

***Even if TP-03 or any other product candidate that we develop receives marketing approval, we may not be successful in educating ECPs and the market about the need for treatments specifically for Demodex blepharitis and other diseases or conditions targeted by our product candidates. TP-03 or other product candidates that we may develop may fail to achieve market acceptance by ECPs, other healthcare providers and patients, or adequate formulary coverage, pricing or reimbursement by third-party payers and others in the medical community, and the market opportunity for these products may be smaller than we estimate.***



If TP-03 or any other product candidate that we are developing or develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by ECPs or other healthcare providers, patients, third-party payers and others in the medical community. There is no approved prescription therapeutic for Demodex blepharitis and current treatments include over-the-counter and off-label remedies such as tea tree oil, lid wipes and artificial tears, as well as off-label prescription products. Efforts to educate the medical community, patients and third-party payers on the benefits of our product candidates may require significant resources and may not be successful.

The NDA for TP-03 for the treatment of Demodex blepharitis was accepted by the FDA, with a PDUFA decision date of August 25, 2023. If TP-03 receives FDA or other regulatory marketing approval, including the treatment of both signs and symptoms of Demodex blepharitis, ECPs and potential patients may not have sufficient information about, or recognize the need for a treatment specifically targeting Demodex blepharitis, it is possible that ECPs may continue to rely on other treatments for treating symptoms consistent with Demodex blepharitis. A key tenet of our commercialization strategy is to educate ECPs on Demodex blepharitis and how to diagnose it with a simple slit lamp examination as well as raise patient awareness of Demodex blepharitis. However, our efforts may prove to be unsuccessful, and we may not be able to develop this new market for which there is no approved treatment. If TP-03 receives FDA or other regulatory marketing approval, we may still not achieve success in promotional efforts for TP-03, and ECPs may continue to use existing treatments rather than TP-03 or any other product candidate and potential patients may not inquire as to TP-03. It is also possible that ECPs and patients may not be willing to adopt TP-03 for the treatment of Demodex blepharitis because of the possibility that the disease will recur despite mite eradication and the potential for periodic use of TP-03.

In addition, if generic versions of any products that compete with any of our product candidates are approved for marketing by the FDA or comparable foreign regulatory authorities, they would likely be offered at a substantially lower price than we expect to offer for our product candidates, if approved. As a result, ECPs, patients and third-party payers may choose to rely on such products rather than our product candidates.

If TP-03 or any other product candidate that we develop does not achieve an adequate level of acceptance, formulary coverage, pricing or reimbursement we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of TP-03 or any other product candidate that we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages of our product candidates compared to alternative treatments, including the existing standard of care, and the perceptions by members of the healthcare community of the same;
- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of ECPs to prescribe these therapies;
- the strength and effectiveness of our marketing and distribution support, which may be adversely impacted by the COVID-19 pandemic;
- publicity concerning our products or competing products and treatments;
- the timing of market introduction of competitive products;
- the perception by patients or physicians that the diseases we are targeting, including Demodex blepharitis, are not burdensome;
- the potential for our competitors to limit our access to the market through anti-competitive contracts or other arrangements;
- the availability of third-party formulary coverage and adequate reimbursement;
- product labeling or product insert requirements of the FDA or other regulatory authorities;

- the prevalence and severity of any side effects; and
- any restrictions on the use of our products, if approved, together with other medications.

***Clinical drug development is a lengthy, expensive and risky process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If clinical trials of our product candidates do not meet safety or efficacy endpoints or are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.***

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. The research and development of drugs is an extremely risky industry. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Failure or delay can occur at any time during the clinical trial process. To date, we have focused substantially all of our efforts and financial resources on identifying, acquiring, and developing our product candidates, including conducting preclinical studies and clinical trials. Clinical testing is expensive and can take many years to complete, and we cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials. Our inability to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates. We currently generate no revenues from sales of any products, and we may never be able to develop or commercialize a marketable product.

The results of preclinical and early clinical trials of our product candidates and other products with the same mechanism of action may not be predictive of the results of later-stage clinical trials. For example, we may not be able to replicate the safety and efficacy results of our Phase 2b/3 clinical trials for Demodex blepharitis in clinical trials for other indications in the future. Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria, relatively smaller sample size in earlier trials, and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. Furthermore, as more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. For example, our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. The failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates or cause regulatory authorities to require additional testing before approving any of our product candidates.

If we are unable to complete preclinical or clinical trials of current or future product candidates, due to safety concerns, or if the results of these trials are not satisfactory to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization. Even if we are able to obtain marketing approvals for any of our product candidates, those approvals may be for indications that are not as broad as desired or may contain other limitations that would adversely affect our ability to generate revenue from sales of those products. Moreover, if we are not able to differentiate our product against other approved products within the same class of drugs, or if any of the other circumstances described above occur, our business would be materially harmed and our ability to generate revenue from that class of drugs would be severely impaired.

Each of our product candidates will require additional clinical development, management of clinical, preclinical (for some of our product candidates) and/or manufacturing activities, regulatory approval in multiple jurisdictions, achieving and maintaining commercial-scale supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We may experience delays in our ongoing

clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. For example, the FDA had initially recommended that for TP-03 we conduct carcinogenicity testing and has subsequently agreed in Type C meeting minutes that we can submit a carcinogenicity waiver, and if not granted, the carcinogenicity testing could be conducted and submitted as a post-marketing requirement. Furthermore, the FDA recommended that we conduct embryofetal development studies in a second species, which have been completed. Any recommendations by the FDA regarding our applications or clinical trials could cause delay of any regulatory approval by the FDA and cause our expenses to increase. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, or any other product candidates that we may develop, including:

- we may experience delays in or failure to reach agreement on acceptable terms with prospective CROs, vendors and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, vendors and trial sites;
- we may fail to obtain sufficient enrollment in our clinical trials, our enrollment needs may grow larger than we anticipate, or participants may fail to complete our clinical trials at a higher rate than we anticipate;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may decide, or regulators or institutional review boards or ethics committees may require us, to 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;
- regulators or institutional review boards or ethics committees may not authorize us or our investigators to commence a clinical trial at a prospective clinical trial site or at all or may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may need to delay or suspend one or more trials until we complete additional financing transactions or otherwise receive adequate funding;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may be delayed;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards or ethics committees to suspend or terminate trials;
- regulatory authorities may determine that the planned design of our clinical trials is flawed or inadequate;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- we may not be able to timely or at all obtain INDs for a product candidate;
- we may modify a preclinical study or clinical trial protocol;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may be unable to establish clinical endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities consider likely to predict clinical benefit;

- we may experience delays due to the outbreak of health pandemics, including with respect to the conduct of ongoing clinical trials, receipt of product candidates or other materials, submission of NDAs, filing of INDs, and starting any clinical trials for other indications or programs; and
- we may experience manufacturing delays due to the recent COVID-19 pandemic in our supply chain caused by a shortage of raw materials, a lack of employees on site at our suppliers due to illness, or a lack of productivity at our suppliers due to local or national government quarantine restrictions on coming to the workplace.

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

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- 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;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

We cannot be certain whether any of our planned clinical trials will begin on schedule or any preclinical studies we plan to initiate will begin on our intended schedule, or whether any such studies or clinical trials will need to be restructured or will be completed on schedule, or at all. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, or are unable to achieve clinical endpoints due to unforeseen events, such as the COVID-19 pandemic, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

***Our product candidates still require significant testing. We only recently began clinical trials to test TP-03 in humans and, as a company, we have limited experience in this area.***

In May 2022, we announced positive topline results from our Saturn-2 trial, our second and final TP-03 pivotal trial, which enrolled 412 subjects. In addition to the completion of the Saturn-2 trial, we have completed four Phase 2 trials and one Phase 2b/3 Saturn-1 trial for the treatment of Demodex blepharitis. Most of our operations to date have been limited to preclinical studies and clinical trials.

Additionally, we are early in our development efforts for certain of our product candidates and indications, including TP-03 for the treatment of MGD, TP-04 for the treatment of rosacea and TP-05 for potential Lyme prophylaxis and community malaria reduction. The risk of failure for product candidates in early development is high. Extensive clinical trials are necessary to demonstrate the safety and efficacy of such product candidates in humans. Clinical trials may fail to demonstrate that such product candidates are safe for humans and effective for indicated uses. Further, we intend to leverage data from the TP-03 preclinical studies and clinical safety assessments for the treatment of Demodex blepharitis to satisfy the preclinical study requirements for TP-03 for the treatment of MGD, and TP-04 and TP-05 and other indications. For MGD, we recently announced the enrollment of our first patient in the Phase 2 Ersu trial studying TP-03 for the potential treatment of MGD and we expect to report topline results during the second half of 2023. For rosacea, we conducted a Phase 1 clinical study with TP-04 and initiated the Galatea trial, a Phase 2a trial for the treatment of rosacea in March 2023. With respect to Lyme disease, in December 2022 we announced positive topline results from the completed Callisto trial and enrollment of the first

patient in the Carpo trial. The Carpo trial, evaluating TP-05 for potential Lyme disease prophylaxis in humans, is a randomized, double-blind trial that will evaluate the efficacy of TP-05 in killing sterile, non-disease carrying ticks after they have attached to the skin of healthy volunteers, as well as confirm the safety, tolerability, and blood concentration of TP-05. Topline data from the Carpo trial is expected in the second half of 2023. The FDA may reject our use of data from TP-03 preclinical studies for the treatment of Demodex blepharitis for other indications or require additional studies to augment the data to advance for clinical development. The FDA may also reject our use of data from preclinical studies conducted by third parties for Lyme disease and require us to conduct additional preclinical studies before advancing to additional clinical trials. In addition, data from preclinical studies conducted by third parties may not be as reliable as data from studies conducted by us and since we did not conduct the studies, there may be weaknesses in the studies design or results that we may not be aware of.

In part because of our limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, we cannot be certain that our clinical trials will be completed on time, that our planned clinical trials will be initiated on time, if at all, that our planned development programs would be acceptable to the FDA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized.

***If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- costs to, or lack of adequate compensation for, prospective patients;
- difficulties of enrolling patients or patients continuing to participate in follow-up visits due to ongoing or new health pandemics; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition would reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Moreover, potential patients and their doctors may be inclined to use existing therapies rather than enroll patients in any future clinical trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

***Our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects which may delay or prevent marketing approval or cause us to abandon or limit further clinical development of those product candidates. In addition, if we obtain approval for any of our product candidates, significant adverse events, toxicities or other undesirable side effects may be identified during post-marketing surveillance, which could result in regulatory action or negatively affect our ability to market the product.***

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the European Commission or other comparable foreign regulatory authorities.

During the conduct of clinical trials, subjects report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, 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, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to subjects on a commercial scale after approval.

Our understanding of the relationship between our product candidates and these adverse events may change as we gather more information, and additional unexpected adverse events or an increase in adverse event rates may occur. If additional clinical experience indicates that any of our product candidates have side effects or causes serious or life-threatening side effects, participant recruitment for trials and the ability of enrolled subjects to complete trials could be negatively impacted, and the development of the product candidate may fail or be delayed, which would severely harm our business, prospects, operating results and financial condition.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw approvals of such product or require additional warnings on the label such as a black box warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- the product may be seized by regulatory authorities;
- there may be a recall of the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create and implement a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, including ECPs, and/or other elements to assure safe use;
- the product may become less competitive;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer and there may be resulting harm to physician or patient acceptance of our product.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

***Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.***

Before we can initiate clinical trials in the United States for our product candidates, we must submit the results of preclinical testing and any previous clinical studies to the FDA along with other information, including information about

product candidate chemistry, manufacturing and controls ("CMC") and our proposed clinical trial protocol, as part of an IND. The initiation of clinical trials in the EU Member States will be subject to similar requirements concerning approval by competent national authorities and the receipt of a positive opinion from the relevant ethics committees. We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities placing the clinical trial on hold;
- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- failure to demonstrate efficacy of the product;
- any interruptions or delays in the supply of our product candidates for our clinical trials;
- a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- any failure or delay in reaching an agreement with CROs, vendors and clinical trial sites;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices ("GCP") or regulatory requirements or other third parties not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred, disqualified or suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications;
- one or more Institutional Review Boards ("IRBs"), other ethics committees refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- changes in regulatory requirements and policies, which may require us to amend clinical trial protocols to comply with these changes and resubmit our clinical trial protocols to IRBs or ethics committees for reexamination.

Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize the commercial prospects of our product candidates and our ability to commence product sales and generate revenue.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. For example, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly. Any termination of any clinical trial of our product candidates will harm our commercial prospects and our ability to generate revenue.



***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates on acceptable terms, we may be unable to successfully commercialize our product candidates that obtain regulatory approval.***

We currently have a limited marketing and sales team. In order to commercialize any product candidates, if approved, we must continue to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell and market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***The sizes of the market opportunities for our product candidates, particularly TP-03 for the treatment of Demodex blepharitis and for the treatment of MGD, have not been established with precision and may be smaller than we estimate, possibly materially. If our estimates of the sizes overestimate these markets, our sales growth may be adversely affected. We may also not be able to grow the markets for our product candidates as intended or at all.***

Our assessment of the potential market opportunity for TP-03 and other product candidates that we develop is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and our own internal epidemiology and market research studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Similarly, although the studies we have conducted are based on information that we believe to be complete and reliable, we cannot guarantee that such information is accurate or complete. The potential market opportunities for the treatment of Demodex blepharitis and for the treatment of MGD is difficult to precisely estimate, because patients often have multiple ocular surface diseases and the symptoms have significant overlap, leading to frequent misdiagnosis of the various conditions. Therefore, our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and our own epidemiology studies and market research, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions and the bases of the studies and research we have conducted are reasonable, no independent source has verified such assumptions or bases. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for TP-03 or any of our other product candidates may be smaller than we expect, and as a result our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

Due to the patients presenting at ECP clinics with multiple ocular surface diseases, there is overlap in market size estimates for blepharitis and MGD. Therefore, if TP-03 receives regulatory approval for the treatment of Demodex blepharitis and MGD, our opportunity could be less than our forecasts because the actual market for TP-03 might be significantly smaller than our estimates.

***We may not be able to demonstrate the safety and efficacy of TP-03, TP-04 and TP-05 in the indications we are pursuing even though the API underlying such product candidates is safe and effective in animals.***

TP-03, TP-04 and TP-05 are presentations of lotilaner, the API, formulated into an eye drop, topical gel and oral formulation, respectively. Lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific GABA-Cl channels, has been found to be safe and effective in animals. However, despite being safe and effective in animals, we may not be able to demonstrate that TP-03, TP-04 and TP-05 are safe and effective for human use in the indications we are pursuing for these product candidates. This may be in part because the requirements and regulations

applicable to approval of a product candidate for human use are significantly more stringent than for animals and that there may be other ocular or other relevant differences between animals and humans.

***We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted. Our product candidates will, if approved, also compete with existing branded, generic and off-label products.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to our product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide and existing treatments. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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 our products. Our competitors also may obtain FDA approval or other regulatory authority approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing 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 payers, particularly Medicare and the competent authorities of the individual EU Member States, seeking to encourage the use of generic products. Generic products are currently being used for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. 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 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.

Additionally, while there are no currently available on-label prescription pharmaceutical treatments available for the treatment of blepharitis or Demodex blepharitis specifically, a number of other treatments are currently available for the treatment of blepharitis in the U.S. Current treatments for blepharitis in the U.S. include over the counter remedies such as tea tree oil, lid wipes and artificial tears, as well as off-label prescription products. If ECPs were to continue to prescribe these other existing treatments instead of TP-03, our business would be adversely affected.

***Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or authorization or commercialize such products outside of the U.S., which would limit our ability to realize their full market potential.***

In order to market any products outside of the U.S., we will need to comply with additional onerous but varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we, or our collaboration partners, fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

***Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties, such as our China Out-License with LianBio. We are evaluating the opportunities for the development and commercialization of our product candidates in other foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities if we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training and the need for language translations;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

For example, the pharmaceutical industry in the China Territory is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in the China Territory regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development of TP-03 by LianBio under the China Out-License and reduce the current benefits we believe are available to us. The China Territory authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by LianBio or our other partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our partner's business activities in the China Territory.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. In some countries, particularly the countries in Europe, 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 drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

***We have conducted a number of our completed clinical trials for our product candidates at sites outside the U.S., and the FDA may not accept data from trials conducted in such locations.***

We have conducted all of our Phase 2 clinical trials outside the U.S., for the treatment of Demodex blepharitis which were conducted in Mexico City, Mexico, at a well-established site for ocular therapy trials. We may in the future choose to conduct other clinical trials outside the U.S. We expect that the FDA will primarily consider the efficacy results of our Saturn-1 and Saturn-2 trials in addition to safety data from all human trials, our preclinical studies data as well as preclinical data for lotilaner in reviewing our NDA submission for TP-03 for the treatment of Demodex blepharitis.

Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from clinical trials conducted outside of the U.S. There can also be no assurance that the comparable foreign regulatory authority in any jurisdiction in which we seek regulatory approval for our product candidates will accept data from clinical trials conducted outside such jurisdiction. If the FDA or any such foreign regulatory authority does not accept the data from any trial that we have conducted outside the U.S., it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the U.S. and if we conduct trials outside of the U.S., we may face risks, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange rate fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries;
- different cultural attitudes to self-reported adverse events (such as burning, stinging, blurry vision) leading to a different safety profile; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

***Even if we obtain regulatory approval with respect to TP-03 for Demodex blepharitis, we may not be able to obtain regulatory approval for additional indications, such as MGD, or we may be required to conduct additional trials, which would limit our ability to realize the full market potential of TP-03 or increase the costs of developing TP-03 for MGD.***

If we obtain regulatory approval with respect to TP-03 for the treatment of Demodex blepharitis, we intend explore the therapeutic potential for TP-03 in MGD as an additional indication. If we are successful, the indication for use of TP-03 could potentially be broadened beyond the treatment of Demodex blepharitis to include MGD as an additional indication. However, there can be no assurance that, even if we obtain approval for Demodex blepharitis, we will obtain approval for any other indication, including MGD or for any broadened indication beyond the treatment of Demodex blepharitis. If we fail to obtain and maintain required approvals for these additional or broadened indications, or if regulatory approvals are delayed, we will not realize the full market potential of TP-03. Additionally, the FDA or other comparable foreign regulatory authority may require us to conduct additional clinical trials before seeking regulatory approval.

***Managing our obligations under our in-license and out-license agreements and other strategic agreements may divert management time and attention, causing delays or disruptions to our business.***

We have entered into two license agreements with Elanco: (i) Eye and Derm Elanco Agreement and (ii) the All Human Uses Elanco Agreement, and have also entered into the China Out-License as discussed elsewhere herein. We also may in the future enter into in-license or out-license agreements with multiple licensors and strategic agreements, which, subject to

to various obligations, including diligence obligations, reporting and notification obligations, payment obligations for achievement of certain milestone as well as other material obligations. We may need to devote substantial time and attention to ensuring that we successfully integrate these transactions into our existing operations and are compliant with our obligations under these agreements, which may divert management's time and attention away from our research and development programs or other day-to-day activities.

Our in-license, out-license, and strategic agreements are also complex and certain provisions in those agreements may be susceptible to multiple interpretations. In the event of any disagreement about the interpretation of these provisions, our management may need to devote a disproportionate amount of its attention to resolving these disagreements. Such disruptions may cause delays in our research and development programs and other business objectives.

***Our operating activities may be restricted by certain covenants in our license and other strategic agreements, which could limit our development and commercial opportunities.***

In connection with our in-license, out-license, or other collaborations or strategic alliances, we may agree to and be bound by negative covenants which may limit our development and commercial opportunities. For example, pursuant to the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement, we made certain covenants to only engage with third party suppliers previously approved by Elanco, and only under certain circumstances. These provisions may inhibit our development efforts, prevent us from forming strategic collaborations to develop and potentially commercialize any other product candidates and may materially harm our business, financial condition, results of operations and prospects.

***We may expend our limited resources to pursue TP-03 for the treatment of Demodex blepharitis and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our product candidates on the potential treatment of certain indications. We are currently focused on the development and commercialization, if approved, of TP-03 for the treatment of Demodex blepharitis. 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 the most viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for TP-03 for the treatment of Demodex blepharitis may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for TP-03, we may also 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.

***Even if we obtain regulatory approvals for any product candidates we develop, the terms of approvals and ongoing regulation of our products could require substantial expenditure of resources and may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.***

Any product candidate for which we obtain regulatory approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to continual requirements of and review by the FDA, the EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

Accordingly, assuming we receive regulatory approval for one or more product candidates we develop, 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 regulatory approvals for our products 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. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

***Interim top-line and preliminary results from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures, which could result in material changes in the final data.***

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary or top-line results 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. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common stock to fluctuate significantly.

#### **Risks Related to Reliance on Third Parties**

***We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.***

We do not have the ability to independently conduct our clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and planned clinical trials of TP-03, TP-04 and TP-05 and other product candidates, and we expect to continue to rely upon third parties to conduct additional clinical trials of potential future product candidates. Third parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third party, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, it would delay our development activities.

Our reliance on these third parties for such development activities will reduce our control over these activities but will not relieve us of our regulatory 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 GCP standards, regulations 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. The EC also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EC or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP or other applicable regulations. In addition, our clinical trials must be conducted with product produced under current applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. In addition, the operations of our CROs and other third-party service providers may be constrained or disrupted by health pandemics, including the COVID-19 pandemic. 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 our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays can occur, which could materially impact our ability to meet our desired clinical development timelines. The COVID-19 pandemic and government measures taken in response have also had a significant impact on many CROs. Although we plan to carefully manage our relationships with our CROs, investigators and

other third parties, we may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, financial condition and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of any product candidates.

***We contract with third parties for the manufacture of our product candidates for preclinical studies, clinical trials and for eventual commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or compounds or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not have any, and have no plans to acquire any, manufacturing facilities. We produce in our laboratory relatively small quantities of compounds for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements and expect that each of our product candidates will only be covered by single source suppliers for the foreseeable future. For example, we purchase our API for TP-03, lotilaner, from Elanco, who sources through a single source supplier. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Furthermore, all entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA on a timely basis and must adhere to the FDA's Good Laboratory Practice regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Foreign regulatory authorities, including the European Commission and the competent authorities of the EU Member States, may require compliance with similar requirements. The facilities and quality systems of our third-party contractor manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP regulations. We have little or no control over the production processes of third-party manufacturers, CMOs or other suppliers. The third-party manufacturing facilities used in the production of API and our drug products are located outside of the U.S. and require FDA approval, which our third-party manufacturers may have limited experience with obtaining. Our CMOs and other suppliers are subject to inspection by the FDA and may receive observations that they may not be able to resolve in a timely or effective manner, which could impact whether our products can be approved on a timely basis, if at all.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we elect to or are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. If any of our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer.



Our or a third party's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- loss of the cooperation of an existing or future collaborator, including by Elanco under the license agreements with Elanco;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

We or our third-party manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredients necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or active pharmaceutical ingredients, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredients by our competitors or others. The failure of us or our third-party manufacturers to obtain the raw materials or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our product candidates, may have a material adverse effect on our business.

***We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from conducting clinical trials and developing our product candidates.***

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or our manufacturing partners, 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. If we, or our manufacturing partners, 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 become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates progress through preclinical to late stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

#### **Risks Related to Intellectual Property**

***The development and commercialization of our products, including our lead product candidate, TP-03 for the potential treatment of Demodex blepharitis and MGD, TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme***

***prophylaxis and community malaria reduction, is dependent on intellectual property we license from Elanco. If we breach our agreements with Elanco or the agreements are terminated, we could lose license rights that are important to our business.***

Pursuant to the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement (each an "Elanco Agreement" and together the "Elanco Agreements") we acquired exclusive, worldwide, sublicensable licenses to certain intellectual property of Elanco for the development, marketing and commercialization of lotilaner for (i) the treatment, prevention, palliation or cure of any eye or skin disease or condition in humans and (b) all other applications in humans, respectively. The Elanco Agreements impose various development, regulatory, commercial diligence, financial and other obligations on us. If we fail to comply with our obligations under the Elanco Agreements, or otherwise materially breach either Elanco Agreement, and fail to remedy such failure or cure such breach within 60 days, Elanco will have the right to terminate the applicable Elanco Agreement. If we fail to meet any milestones by the achievement deadlines set forth in either Elanco Agreement for any reason other than those outside of our reasonable control, and such milestones remain unmet for 120 days after Elanco notifies us thereof, Elanco may terminate the applicable Elanco Agreement.

If we fail to meet certain dermatological milestones by the achievement deadlines set forth in the Eye and Derm Elanco Agreement for any reasons other than those outside of our reasonable control, and such milestones remain unmet for 120 days after Elanco notifies us thereof, Elanco may limit our field of use under the Eye and Derm Elanco Agreement to the treatment, palliation, prevention or cure of eye diseases or conditions in humans only. If either Elanco Agreement is terminated or if our field of use in the Eye and Derm Elanco Agreement is reduced to eye and skin conditions only by Elanco, we would lose our applicable license in the country where such license was terminated and all rights therein to the licensed intellectual property would revert to Elanco. The loss of the license from Elanco would prevent us from developing and commercializing TP-03, TP-04 and TP-05 in any country where the license is terminated and could subject us to claims of breach of contract and patent infringement by Elanco if any continued research, development, manufacture or commercialization of TP-03, TP-04 or TP-05 is covered by the affected patents. If Elanco terminates the Eye and Derm Elanco Agreement for our failure to achieve a development milestone by the specified achievement deadline, then we must grant Elanco a non-exclusive, sublicensable, royalty-free license to our patents and know-how relating to lotilaner to develop, manufacture and commercialize lotilaner and any licensed products for the treatment, palliation, prevention or cure of any eye or skin disease or condition in humans. If Elanco terminates the All Human Uses Elanco Agreement for our failure to achieve a development milestone by the specified achievement deadline, then we must grant Elanco a non-exclusive, sublicensable, royalty-free license to our patents and know-how relating to lotilaner to develop, manufacture and commercialize lotilaner and any licensed products for all applications in humans other than the treatment, palliation, prevention or cure of any eye or skin disease or condition. Accordingly, the loss of our license or the termination of our license for skin diseases and conditions or of our license for other use in humans with Elanco would materially harm our business.

***If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.***

We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to our development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our product candidates and research programs. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued that protect our product candidates or their intended uses or that effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions,

including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the scope of patent protection outside of the U.S. is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the U.S., or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing or will pursue will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our ability to commercialize our products, is highly uncertain. Because we have not yet conducted a formal patent landscape analysis related to our product candidates, we may not be aware of issued patents that a third party might assert are infringed by one of our current or future product candidates, which could materially impair our ability to commercialize our product candidates. Even if we diligently search third-party patents for potential infringement by our products or product candidates, including TP-03, TP-04 or TP-05, we may not successfully find patents that our products or product candidates, including TP-03, TP-04 or TP-05, may infringe. If we are unable to confirm that our products do not infringe third-party patents, others could preclude us from commercializing our product candidates. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing or, in some cases, not published at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patents or pending patent applications may be challenged in the courts or patent offices in the U.S. and abroad. For example, we may be subject to a third party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in post-grant review or interference procedures, oppositions, derivations, revocations, reexaminations, or inter partes review proceedings, in the U.S. 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 drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Our owned and licensed patent estate includes patent applications, many of which are at an early stage of prosecution. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or ability to sell our products without infringing third-party patents or 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 products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and product candidates.

Furthermore, while we seek to protect the trademarks we use in the U.S. and in other countries, we may be unsuccessful in obtaining registrations and/or otherwise protecting these trademarks. If that were to happen, we may be prevented from using our names, brands and trademarks unless we enter into appropriate royalty, license or coexistence agreements, which may not be available or may not be available on commercially reasonable terms. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, service marks and domain names, then we may not be able to compete effectively, resulting in a material adverse effect on our business. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted or declared generic, or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trademarks and trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered

trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Effective trademark protection may not be available or may not be sought in every country in which our products are made available. Any name we propose to use for our products in the U.S. 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 potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, that does not infringe the existing rights of third parties and that is acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications relating to our product candidates, our competitive position, business, financial condition, results of operations and prospects would be adversely affected.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our products.***

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the U.S. and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Because we have not yet conducted a formal patent landscape analysis related to our product candidates, we may not be aware of issued patents that a third party might assert are infringed by one of our current or future product candidates, which could materially impair our ability to commercialize our product candidates. Even if we diligently search third-party patents for potential infringement by our products or product candidates, we may not successfully find patents that our products or product candidates may infringe. If we are unable to confirm that our products do not infringe third-party patents, others could preclude us from commercializing our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

***We may wish to acquire rights to future assets through in-licensing or may attempt to form collaborations in the future with respect to our product candidates, but may not be able to do so, which may cause us to alter or delay our development and commercialization plans.***

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. In 2019 and 2020, we entered into the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement, respectively. We plan to utilize these license rights in developing and marketing our TP-03, TP-04 and TP-05 product candidates. We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of those product candidates. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative

arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the following:

- the design or results of clinical trials;
- the likelihood of approval by the FDA or comparable foreign regulatory authorities;
- the potential market for the product candidate;
- the costs and complexities of manufacturing and delivering such product candidate to patients;
- the potential of competing products;
- the existence of uncertainty with respect to our ownership of technology or other rights, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally.

The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations that we have entered into and may enter in the future may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that divert resources or create competing priorities;
- collaborators may not pursue commercialization of any product candidates that achieve marketing approval or may elect not to continue or renew commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- a collaborator may seek to renegotiate or terminate their relationship with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our collaborators.

***In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms or we may fail to comply with our obligations under such agreements and our business could be harmed.***

In addition to the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement, from time to time we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to

manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all.

If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under any license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. In each of the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement, Elanco retains, and future licensors could retain, the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce such licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. If our licensors do not adequately protect such licensed intellectual property, competitors may be able to use such intellectual property and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates and delay or render impossible our achievement of profitability. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

In addition to the above risks, intellectual property rights that we license in the future may include sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

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 intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- 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 agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

***We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that our patents or patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.***

Although we have pending U.S. and foreign patent applications in our portfolio, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those claimed in our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the U.S. or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the U.S. or foreign countries.

***If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.***

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other



legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time consuming and, even if resolved in our favor, are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. 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 market price of our common stock.

Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and biopharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents are directed to various types of products or methods of use. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties. The scope of patents is subject to interpretation by the courts, and the interpretation is not always uniform. The legal threshold for initiating litigation or contested proceedings is low, so even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the U.S., proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any 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 and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. 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. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

***If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.***

In the U.S., the term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the U.S. or in any foreign country 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 term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

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

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. To counter infringement or unauthorized use, we may be required to file infringement or other intellectual property-related claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from making, using, or selling the invention at issue. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable. There is also a risk that, even if the validity of such patents is 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 making, using or selling the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, 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, which could materially harm our business and negatively affect our position in the marketplace.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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. There also could be public announcements of 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 material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. 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.

***Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.***

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

***Changes in patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act (“Leahy-Smith Act”) signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a nonexclusive, nontransferable, irrevocable, paid-up license for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights”. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a nonexclusive, partially exclusive, or exclusive license to a responsible applicant or applicants. If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co-own or license in technology that is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Further, 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 pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Furthermore, certain foreign and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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.

***We may rely on trade secret and proprietary know how which can be difficult to trace and enforce, and if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements

of our product candidate, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Despite these efforts, our assignment agreements may not be self-executing and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially, and adversely affect our business, financial condition, results of operations, and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees. The assignment risks of this paragraph could also pertain to any intellectual property licensed-in to us. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them 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 or other third party, our competitive position would be harmed.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.***

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies, or at research institutions. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We or our licensors may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- the Supreme Court of the U.S., other U.S. federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our or our licensors' patents;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

***Patent terms may be inadequate to protect our competitive position on our product candidates and preclinical programs for an adequate amount of time.***

Patent rights are of limited duration. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. A patent term extension based on regulatory delay may be available in the U.S. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. 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 product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

**Risks Related to Government Regulation**

***Our industry is highly regulated by the FDA and comparable foreign regulatory agencies. We must comply with extensive, strictly enforced regulatory requirements to develop, obtain, and maintain marketing approval for any of our product candidates.***

Any product candidates we develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution are very heavily regulated. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing FDA or comparable foreign regulatory approval such as a marketing authorization from the European Commission or the competent authorities of the individual EU Member States, requires the submission of extensive preclinical and clinical data and supporting information for each therapeutic indication to establish the product candidate's safety and efficacy for its intended use. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. It takes years to complete the testing of a new drug and development delays and/or failure can occur at any stage of testing. Any of our present and future clinical trials may be delayed, halted, not authorized, or approval of any of our products may be delayed or may not be obtained due to any of the following:

- any preclinical study or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or comparable foreign regulatory authorities;
- preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent marketing approval;
- negative or inconclusive results from a preclinical study or clinical trial or adverse events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a development program to be terminated, even if other studies or trials relating to the development program are ongoing or have been completed and were successful;
- the FDA or comparable foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that subjects enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- the facilities that we utilize, or the processes or facilities of third-party vendors, including without limitation the contract manufacturers who will be manufacturing drug substance and drug product for us or any potential collaborators, may not satisfactorily complete inspections by the FDA or comparable foreign regulatory authorities; and
- we may encounter delays or rejections based on changes in FDA regulations, standards or policies or the regulations, standards or policies of comparable foreign regulatory authorities during the period in which we develop a product candidate or the period required for review of any final marketing approval before we are able to market any product candidate.

In addition, information generated during the clinical trial process is susceptible to varying interpretations that could delay, limit, or prevent marketing approval at any stage of the approval process.

Moreover, early positive preclinical or clinical trial results may not be replicated in later clinical trials. As more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Failure to demonstrate adequately the quality, safety and efficacy of any of our product candidates would delay or prevent marketing approval of the applicable product candidate. We cannot assure you that if clinical trials are completed, either we or our potential collaborators will submit applications for required authorizations to manufacture or market potential products or that any such application will be reviewed and approved by appropriate regulatory authorities in a timely manner, if at all. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application.

**Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.**

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, impact pricing and reimbursement and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payers both federally and on the state level in the U.S. and elsewhere, including in the European Union, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Affordable Care Act substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (i) introduced a new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (iii) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (iv) expanded the list of covered entities eligible to participate in the 340B drug pricing program; (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased from 50% in 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D (which, under the IRA, will be replaced by a new manufacturer discount program starting in 2025); (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vii) created a licensure framework for follow on biologic products; and (viii) established a Center for Medicare & Medicaid Innovation, CMMI, at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial challenges to certain aspects of the Affordable Care Act, as well as efforts by Congress to modify, and agencies to alter the implementation of, certain aspects of the Affordable Care Act. For example, Congress eliminated, starting January 1, 2019, the tax penalty for not complying with the Affordable Care Act's individual mandate to carry health insurance. Further, the Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In the future, Congress may consider other legislation to modify elements of the Affordable Care Act or other health care reform measures, agencies may further alter their implementation of elements of the Affordable Care Act or other such measures, and other judicial challenges to elements of the Affordable Care Act or other such measures may be brought. The extent to which any such changes may impact our business or financial condition is uncertain.

It is possible that the ACA, as currently enacted or may be amended in the future, as well as other healthcare reform measures including those that may be adopted in the future, may result in more rigorous coverage criteria, and less favorable payment methodologies, or other downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement or restriction on coverage under Medicare or other government programs may result in a similar reduction or restriction by private payers.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which went into effect on April 1, 2013. Subsequent legislation extended the 2% reduction, generally to 2031. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. ATRA among other things, also reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and related services and, accordingly, the results of our financial operations. Additional changes that may affect our



business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") which first affected physician payment in 2019. It is unclear how the introduction of the Medicare quality payment program will impact our business.

The IRA introduces several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs and a change in manufacturer liability under the program which could negatively affect the profitability of our product candidates. The IRA sunsets the current Part D coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA establishes a Medicare Part B inflation rebate scheme effective January 2023 and a Medicare Part D inflation rebate scheme effective October 2022, under which, generally speaking, manufacturers will owe rebates if the price of a Part B or Part D drug increases faster than the pace of inflation. Failure to timely pay a Part B or D inflation rebate is subject to a civil monetary penalty. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologicals without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. This or any other legislative change could impact the market conditions for our products.

There has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills and initiatives, as well as state efforts, 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 drug products. Individual states in the U.S. have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

We expect that these and other healthcare reform measures in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may hinder us in generating revenue, attaining profitability or commercializing our drugs, once marketing approval is obtained.

In the European Union, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of EU Member States. The requirements may differ across the EU Member States. In markets outside of the U.S. and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Also, at national level, actions have been taken to enact transparency laws regarding payments between pharmaceutical companies and health care professionals.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the U.S., the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

***Our employees, independent contractors, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the U.S. and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of



drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity 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 comply with such laws or regulations. We adopted a code of conduct applicable to all of our employees immediately following the completion of our IPO, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity 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 comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

***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 have a material adverse effect on the success of our business.***

We, and the third parties with whom we share our facilities, 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. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of 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. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain general liability insurance as well as 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, hazardous or radioactive 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 and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations. For example, we source our API for TP-03, lotilaner, from Elanco, who sources through a single source supplier. If such manufacturers become subject to such injunctions or sanctions due to non-compliance, it could delay, prevent or impair our development or commercialization efforts, which could have an adverse effect on our business.

***We will be subject to federal, state and foreign healthcare and abuse laws and false claims laws, as well as information privacy and security laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties, criminal sanctions, contractual damages, reputational harm, and diminished profits and future earnings.***

ECPs and third-party payers will play a primary role in the recommendation and prescription of any future product candidates we may develop and any product candidates for which we obtain marketing approval. Our arrangements with ECPs, patients, third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect our business or financial arrangements and relationships through which we would market, sell and distribute our products. As a biopharmaceutical company, federal and state healthcare laws and regulations pertaining to fraud and abuse are applicable to our business and may affect our ability to operate. These laws are further described in the section titled "Business - Government Regulation - Other Regulatory Matters."

We have entered into consulting and scientific advisory board arrangements with physicians and other ECPs, including some who could influence the use of our product candidates, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use our product candidates, if approved, to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Various state and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Efforts to ensure that our collaborations or business arrangements with third parties, and our business generally, comply with applicable healthcare laws and regulations will likely be costly. 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 and regulations. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations.

***Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. 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. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.***

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as Trade Laws, prohibit, among other things, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

***Even if we receive marketing approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved.***

Obtaining coverage and reimbursement approval for a product from a government or other third-party payer is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payer. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the U.S.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations.

Coverage and reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payer, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payers to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Outside of the U.S., many countries require approval of the sale price of a product before it can be marketed and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

***Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), significant fines, private litigation, and/or adverse publicity and could negatively affect our financial condition, operating results and business.***

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act (“FTC 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 collaborators. 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. Though we are not directly subject to HIPAA information privacy and security provisions – other than with respect to providing certain employee benefits, depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Furthermore, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California has enacted the CCPA, which created new transparency requirements, granted to California consumers (as that term is broadly defined) several new rights with regard their personal information, and placed increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, and provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for certain data breaches. In addition, in November 2020, California voters approved the CPRA which introduced significant amendments to the CCPA and established and funded the CPPA. The amendments introduced by the CPRA went into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or potential statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and potential damages. The CCPA could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and have been proposed and enacted in other states.

The Federal Trade Commission (“FTC”) also sets expectations for failing to take appropriate steps to keep consumers’ personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the FTC Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers’ personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. EU Member States and the United Kingdom (“UK”), as well as other jurisdictions where we may in the future operate, have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU General Data Protection Regulation (“GDPR”) imposes

certain obligations and restrictions on the ability to collect, analyze and transfer personal data, including to health-related information from clinical trials. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the processing details disclosed to the individuals, the sharing of personal data with third parties, the transfer of personal data out of the EU, contracting requirements (such as with clinical trial sites and vendors), and security breach/incident notifications. Failure to comply with the GDPR may result in substantial fines (for the most serious breaches of up to EUR 20 million or 4% of the annual global revenue of a noncompliant company, whichever is greater) and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers, or to alleviate problems caused by such breaches. This may be onerous and if our efforts to comply with the GDPR or other applicable EU laws and regulations are not successful, it could adversely affect our business. Recent scrutiny and reevaluation of legal mechanisms to allow for the transfer of personal data from the EEA, Switzerland, or UK to the U.S. may impact our ability to transfer personal data or otherwise may cause us to incur significant costs to do so legally. Although there are legal mechanisms to allow for the transfer of personal data from the EEA, Switzerland, and the UK to the U.S., uncertainty about compliance with EU data protection laws remains and data protection authorities from the different EU Member States may interpret the GDPR differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the European Union. Enforcement by EU and UK regulators is generally active, and failure to comply with the GDPR or applicable Member State/UK local law may result in substantial fines, amongst other things (such as notices requiring compliance within a certain timeframe). Further, the UK Government may amend/update UK data protection law, which may result in changes to our business operations and potentially incur commercial cost.

Additionally, European/UK data protection laws, including the GDPR, generally restrict the transfer of personal data from the EEA, including the EU, United Kingdom and Switzerland, to the U.S. and most other countries (except those deemed to be adequate by the European Commission/UK Secretary of State as applicable) unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. While previously U.S. companies could rely on self-certification to the EU-U.S. and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce as one of these safeguards to legitimize transfers from the EU and Switzerland to the US, this has been invalidated by the Court of Justice of the European Union (“CJEU”). The CJEU found that the Standard Contractual Clauses (“SCCs”), one of the primary safeguards for legitimizing data transfers, were valid in principle, but placed obligations on the parties entering into them including to verify whether an adequate level of protection is provided in the recipient jurisdiction, and whether additional measures are required to bring the level of protection in line with EU standards. Following this decision, the European Data Protection Board issued guidance on how organizations should approach international data transfers of GDPR-covered personal data, including the supplemental measures companies can adopt to help protect against overarching surveillance outside of the EU. In June 2021, the European Commission adopted a new set of SCCs aimed at enabling lawful transfers of personal data to non-adequate countries outside the EEA, the deadline for the adoption of which was the 27 December 2022. There are also recent developments regarding data transfers in the UK, which formally approved two mechanisms for transferring UK data overseas and that came into force on 21 March 2022: the International Data Transfer Agreement or the International Data Transfer Addendum to the SCCs. The UK Information Commissioner’s Office also issued guidance on how to approach undertaking risk assessments for transfers of UK data to non-adequate countries outside the UK.

A lack of valid transfer mechanisms for GDPR-covered data could increase exposure to enforcement actions as described above, and may affect our business operations and require commercial cost (including potentially limiting our ability to collaborate/work with certain third parties and/or requiring an increase in our data processing capabilities in the EU/UK). Further, the European/UK data protection laws (including laws on data transfers as set out above) may also be updated/revised, accompanied by new guidance and/or judicial/regulatory interpretations, which could entail further impacts on our compliance efforts and increased cost.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), significant fines, private litigation, and/or adverse publicity and could negatively affect our financial condition, operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals’ privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. We cannot assure you that our third-party service providers with access to our or our customers’, suppliers’, trial patients’ and employees’ personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly.

***If we are able to successfully commercialize any of our products and if we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, failure to comply with obligations under these programs could result in additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

If we successfully commercialize any of our product candidates, we may participate in the Medicaid Drug Rebate Program, the 340B Program, and the VA/FSS program. More details about these programs are included in the section titled "Business - Government Regulatory - Coverage and Reimbursement".

If we fail to comply with any applicable obligations under governmental pricing programs that we participate in, we could be subject to significant civil monetary penalties, or other adverse consequences and those could negatively impact our business, financial condition, results of operations and growth prospects.

#### **Risks Related to Ownership of our Common Stock**

***The stock price of our common stock may be volatile or may decline regardless of our operating performance and you could lose all or part of your investment.***

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- our failure to achieve product development or commercialization goals or regulatory approval milestones in the timeframe we announce;
- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- delays in the commencement, enrollment and the ultimate completion of clinical trials;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory actions with respect to our product candidates;
- regulatory or legal developments in the U.S. and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- changes in hospital or ECP practices;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry, including conditions resulting from COVID-19;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- financing or other corporate transactions, or inability to obtain additional funding;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;

- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float; and
- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many biopharmaceutical companies. Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If securities or industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

***We are an "emerging growth company" and "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an emerging growth company as defined in the Jumpstart our Business Startups Act of 2012, as amended (the "JOBS Act") and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- the option to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act of 2002, as amended (the "Sarbanes Oxley Act");
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation; and
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes."

The JOBS Act permits an emerging growth company such as us, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected to opt out of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted.

We cannot predict if investors will find our common stock less attractive because we will 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. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) December 31, 2025, the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (b) the last day of the fiscal year (a) in which we have total annual gross revenue of at least \$1.235 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of

the prior June 30th and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. 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 take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

Investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. 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 decline or become more volatile.

***Sales of a substantial number of shares of our common stock in the public market could cause the price of our common stock to fall.***

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to decline. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 9, 2023, we had 26,731,663 shares of common stock outstanding. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements.

We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding warrant or options, or the perception that such sales may occur, could adversely affect the market price of our common stock. We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, including pursuant to our ATM program, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. For example, in May 2022 we sold 5.9 million shares of our common stock for gross proceeds of approximately \$79.5 million (before underwriting discounts, commissions and other estimated offering expenses). To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

***The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.***

As of December 31, 2022, our officers, directors and the holders of more than 5% of our outstanding stock collectively beneficially own approximately 53% of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

***Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.***

As a public company, we are subject to the reporting requirements of the Exchange Act, or the other rules and regulations of the Securities and Exchange Commission (the "SEC"), or any securities exchange relating to public companies. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management and we will incur significant legal, accounting and other expenses. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more



difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.***

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market ("Nasdaq"). The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. We must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Therefore, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engaging outside consultants, continue 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. This requires us to incur substantial professional fees and internal costs to maintain compliance.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities including equivalent foreign authorities.

***We do not intend to pay dividends for the foreseeable future.***

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Our Credit Facility also contains a negative covenant that prohibits us from paying dividends subject to limited exceptions. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.***

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Our operating results may fluctuate due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit patients for preclinical studies and clinical trials, and any delays caused by difficulties in such recruitment efforts;

- our ability to obtain regulatory approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- the changing and volatile U.S., European and global economic environments, including the impact of current or future health pandemics; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

***Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.***

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our certificate of incorporation will further provide that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. 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. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

#### **Item 1B. Unresolved Staff Comments.**

None.

#### **Item 2. Properties.**

We currently lease approximately 27,807 square feet of office and laboratory space in Irvine, California under certain leases that expire in January 2024, with a renewal option for a term of three years. We believe that this space will be

sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms.

**Item 3. Legal Proceedings.**

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

**Item 4. Mine Safety Disclosures.**

None.

## PART II

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

Our common stock has been publicly traded on the Nasdaq under the symbol "TARS" since our IPO on October 15, 2020. Prior to this date, there was no public market for our common stock.

#### Holder of Common Stock

As of March 9, 2023, the closing price of our common stock on the Nasdaq was \$14.91 per share, and there were approximately 30 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

#### Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future.

#### Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with our Annual Meeting of Stockholders within 120 days after December 31, 2022 and is incorporated in this Annual Report on Form 10-K by reference.

#### Recent Sales of Unregistered Securities

None.

#### Use of Proceeds from Initial Public Offering

On October 16, 2020, our Registration Statement on Form S-1 (File No. 333-249076) (the "Registration Statement") relating to the initial public offering of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 6,325,000 shares of our common stock, which included 825,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a price of \$16.00 per share. The aggregate offering price for shares sold in the offering was \$101.2 million. On October 20, 2020, we closed the sale of such shares, resulting in aggregate cash proceeds to us of \$91.7 million, net of underwriting discounts, commissions and offering expenses paid or payable by us. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates. BofA Securities, Inc., Jefferies LLC and Raymond James & Associates, Inc., LifeSci Capital LLC and Ledenburg Thalman & Co. Inc., acted as the joint book-running managers of the offering.

There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus, dated October 15, 2020, filed with the SEC on October 16, 2020, pursuant to Rule 424(b) of the Securities Act.

#### Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

### Item 6. Reserved

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our "Selected Financial Data" and our financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including, but not limited to, those discussed under the section titled "Risk Factors" and elsewhere in this Annual Report on 10-K. See the section titled "Special Note Regarding Forward-Looking Statements" elsewhere in this Annual Report on Form 10-K.*

### Overview

#### Our Business

We are a biopharmaceutical company focused on the development and commercialization of therapeutics, starting with eye care. Our lead product candidate, TP-03 (lotilaner ophthalmic solution, 0.25%), is a novel investigational eye drop to treat blepharitis caused by the infestation of Demodex mites, which is referred to as Demodex blepharitis. Blepharitis ("Blephar" is a reference to eyelid and "itis" is a reference to inflammation) is an ophthalmic lid margin disease characterized by inflammation of the eyelid margin, redness and ocular irritation, including a specific type of eyelash dandruff called collarettes, which are pathognomonic for Demodex blepharitis. Poorly controlled and progressive blepharitis can lead to corneal damage over time and, in extreme cases, blindness. There may be as high as approximately 25 million people in the U.S. who suffer from Demodex blepharitis.

We designed TP-03 to target and eradicate the root cause of Demodex blepharitis – Demodex mite infestation. The API of TP-03, lotilaner, paralyzes and eradicates mites and other parasites through the inhibition of parasite-specific GABA-Cl channels.

We intend to further advance our pipeline with lotilaner API to address several diseases across therapeutic categories in human medicine, including eye care, dermatology, and other diseases. We are developing product candidates to address targeted diseases with high unmet medical needs, which currently include TP-03 for the potential treatment of MGD, TP-04 for the potential treatment of rosacea, and TP-05 for potential Lyme disease prophylaxis and community malaria reduction.

#### Recent Business Highlights

##### TP-03 Demodex Blepharitis:

To date, we have completed seven clinical trials that include a Phase 1 trial, four Phase 2 trials, a Phase 2b/3 Saturn-1 trial, and a Phase 3 Saturn-2 trial for TP-03 in Demodex blepharitis, all of which met their primary, secondary and/or certain exploratory endpoints, with the drug well tolerated. In November 2022, we announced that the NDA submission package for TP-03 for the treatment of Demodex blepharitis was accepted by the FDA, with a PDUFA decision date of August 25, 2023. We believe TP-03 has the potential to be the first therapeutic approved by the FDA and become the definitive standard of care for the treatment of Demodex blepharitis.

During 2022, we began the expansion of our commercial organization to support our business growth and the commercial leadership needed for TP-03 commercial launch readiness in the second half of 2023. We expect this commercial expansion to continue with a meaningful ramp during 2023 as part of our TP-03 commercial launch-readiness activities.

##### TP-03 Meibomian Gland Disease:

In August 2022, we announced the enrollment of our first patient in the Ersä trial studying TP-03 for the treatment of MGD. We expect to report topline data during the second half of 2023.

##### TP-03 China Territory Out-License:

In March 2021, we executed the China Out-License with LianBio, granting exclusive commercial rights to TP-03 for the treatment of Demodex blepharitis and MGD within the China Territory. In November 2022, LianBio announced the dosing of their first patient in the TP-03 Phase 3 LIBRA pivotal trial in Chinese patients for the treatment of Demodex blepharitis to support regulatory approval in China.

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To date, we received contractual cash proceeds from LianBio totaling \$80.0 million, representing initial consideration of \$15.0 million and \$65.0 million for the achievement of specified milestone events. We also received equity in LianBio as part of our China Out-License, a portion of which remains subject to a China-based regulatory vesting provision.

We are further eligible to receive:

- China-based development milestones totaling \$25.0 million (includes \$2.5 million for a milestone triggered in February 2023);
- Sales threshold milestones in the China Territory totaling \$100.0 million; and
- Tiered low-to-high teen royalties on the net sales of TP-03 within the China Territory.

**TP-04 Rosacea, Galatea Trial:**

In March 2023, we initiated the Galatea trial, a Phase 2a trial evaluating TP-04, a novel gel formulation of lotilaner, for the treatment of rosacea.

**TP-05 Lyme Disease, Callisto and Carpo Trials:**

In December 2022, we announced positive topline results from the completed Phase 1 Callisto trial and enrollment of the first patient in the Phase 2a Carpo trial. The Callisto and Carpo trials are designed to evaluate TP-05, a novel investigative oral, non-vaccine pharmacological prophylactic for the potential prevention of Lyme disease. The Callisto Phase 1 trial was a randomized, double-blind, single and multiple-ascending dose trial that evaluated the safety, tolerability, and PK of TP-05 in healthy subjects. Results from the trial showed that TP-05 was well tolerated with no dose-related or drug-related serious adverse events. Pharmacokinetic data from the trial demonstrated rapid absorption and an extended half-life of TP-05 that potentially supports a convenient oral therapy regimen, supporting its potential as a rapid onset, prophylactic therapy for Lyme disease. Additionally, exploratory ex-vivo tick kill modeling utilizing a serum from TP-05 treated subjects demonstrated potent, rapid killing of adult and nymph ticks. The Carpo trial, evaluating TP-05 for the potential prevention of Lyme disease in humans, is a randomized, double-blind trial that will evaluate the efficacy of TP-05 in killing lab grown, non-disease carrying ticks after they have attached to the skin of healthy volunteers, as well as confirm the safety, tolerability, and blood concentration of TP-05. We expect to report topline data from the Phase 2a Carpo trial during the second half of 2023.

We believe TP-05 is currently the only non-vaccine, drug-based, prophylaxis in development that targets the ticks, and potentially prevents Lyme disease transmission. It is designed to rapidly and durably provide systemic blood levels of lotilaner potentially sufficient to kill infected ticks attached to the human body before they can transmit the *Borrelia* bacteria that causes Lyme disease.

**Credit Facility with Hercules Capital and Silicon Valley Bank:**

On February 2, 2022 we executed the Credit Facility Hercules Capital and SVB. On January 5, 2023, the Company entered into an amendment to the loan and security agreement, which set a maximum interest rate, and updated the terms of prepayment under the Credit Facility and other certain specific conditions (see *Note 10*).

As of December 31, 2022, the Credit Facility provides for a remaining aggregate principal amount of up to \$135.0 million, with tranching availability as follows: \$25.0 million upon NDA submission of TP-03, \$35.0 million upon FDA approval of TP-03, and \$75.0 million upon achievement of certain revenue thresholds and other conditions. On March 15, 2023, we made a \$5.0 million draw (including SVB's commitment of \$1.25 million) from the \$25.0 million tranche that became available upon submission of the NDA.

Capital draws, at our election, are in \$5.0 million increments. This credit facility includes a four-year interest only period and is extendable to five years upon meeting certain conditions. There is no warrant coverage to the lenders.

**Follow-On Public Offering:**

In May 2022, we completed a follow-on public offering under our effective Form S-3 shelf registration statement through an initial underwritten sale of 5,600,000 shares of common stock at a price of \$13.50 per share (the "Follow-On Public Offering"). We also granted the underwriters a 30-day option to purchase up to 840,000 additional shares of common stock at the public offering price, less discounts and commissions. In June 2022, the underwriters partially exercised this option by purchasing an additional 289,832 shares of common stock at \$13.50 per share.



After giving effect to the exercise of the underwriters' option, the total number of shares of our common stock sold in the Follow-On Public Offering was 5,889,832 shares which resulted in total gross proceeds of \$79.5 million before underwriting discounts, commissions and other estimated offering expenses for total net proceeds of \$74.3 million.

#### **Impact of the COVID-19 Pandemic on our Operations**

Efforts to contain the spread of COVID-19 in the U.S. (including in California where our corporate headquarters and laboratory facility are located) and other countries have included quarantines, shelter-in-place orders, and various other government restrictions in order to control the spread of this virus.

We have been carefully monitoring the COVID-19 pandemic as it continues to progress and its potential impact on our business. We have taken important steps to ensure the workplace safety of our employees when working within our laboratory and administrative offices, or when traveling to our clinical trial sites. We have also implemented a vaccination policy and we may take further actions as may be required by federal, state or local authorities.

To date, we have been able to continue our key business activities and advance our clinical programs. However, in the future, it is possible that our clinical development timelines and business plans could be adversely affected. We maintain regular communication with our vendors and clinical sites to appropriately plan for, and mitigate, the impact of the COVID-19 pandemic on our operations. Specifically, for our Phase 3 Saturn-2 trial, we have instituted various protocols for our sites, including increasing health screening of individuals and providing enhanced communication and training to staff regarding COVID-19. However, the ultimate effect from this pandemic on our development timelines for TP-03 and our other product candidates is inherently uncertain.

See the section titled *Risk Factors* in this report for a further discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

#### **Corporate and Financial Overview**

We were incorporated as a Delaware corporation in November 2016, and our headquarters is located in Irvine, California. Since our inception, we have devoted substantially all of our resources to organizing and staffing our company, acquiring intellectual property, clinical development of our product candidates, building our research and development capabilities, raising capital, and enhancing our corporate infrastructure.

To date we have financed our operations through private placements of preferred stock, convertible promissory notes, the net proceeds from issuance of common stock in our IPO and Follow-On Public Offering, cash proceeds from our China Out-License, and draw-downs from our Credit Facility.

We have incurred significant net operating losses in every year since our inception and expect to continue to incur significant operating expenses and, other than the effect of license fee revenue and collaboration revenue from the China Out-License, increasing operating losses for the foreseeable future. Our net loss was \$62.1 million and \$13.8 million for the years ended December 31, 2022 and 2021, respectively. Our net losses may fluctuate significantly from quarter to quarter and year to year and could be substantial. We anticipate that our operating expenses will increase significantly as we:

- seek regulatory approvals for TP-03 and other product candidates that successfully complete clinical development, if any;
- advance the clinical development of TP-03 for the treatment of MGD, TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme prophylaxis;
- establish our own sales force in the U.S. to commercialize TP-03 upon regulatory approval and our other products for which we obtain such approvals;
- engage with contract manufacturers to ensure a sufficient supply chain capacity to provide commercial quantities of any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, technical, regulatory, marketing, operations, financial, and other support personnel, to execute our business plan; and



- add information systems and personnel to support our product development and potential future commercialization efforts, and to enable us to operate as a public company.

We do not yet have revenue from product sales. Our reported revenue within license fees and collaboration revenue is from our China Out-License; we expect to report additional revenue under these captions in future periods.

We do not expect to generate revenues from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate and commercially launch such product. Until such time as we can generate significant revenue from product sales and achieve profitability, if ever, we expect to finance our operations through private or public equity or debt financings, or collaborations, strategic alliances, or licensing arrangements with third parties. Adequate funding may not be available to us when needed on acceptable terms, or at all. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital or enter into such agreements as and when needed, we could be forced to significantly delay, scale back, or discontinue our product development and/or commercialization plans, which would negatively and adversely affect our financial condition.

Because of the numerous risks and uncertainties associated with drug product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels.

As of December 31, 2022, our aggregate cash, cash equivalents and marketable securities was \$217.0 million – see "*Liquidity and Capital Resources*."

## **Components of our Results of Operations**

### ***License Fees and Collaboration Revenue***

We recognize license fees and collaboration revenue as identified performance obligations are satisfied or other events occur, specifically related to (i) TP-03 pivotal trial completion and the delivery of associated clinical data and reports to our licensee, (ii) achievement of certain clinical and regulatory events in the China Territory, (iii) milestone achievement of a drug supply agreement execution, and (iv) royalties and milestones from our licensee's product sales of TP-03 in the China Territory.

### ***Cost of License Fees and Collaboration Revenue***

Cost of license fees and collaboration revenue includes (i) the proportion of expense recognized under the terms of the China Out-License payable under the terms of our in-license agreement for lotilaner, and (ii) valuation adjustments to the equity warrants and LianBio common stock for the portion contractually due under our January 2019 in-license agreement.

### ***Research and Development Expenses***

Research and development expenses consist of expenses incurred in connection with the development of our product candidates, including:

- fees paid to third parties to conduct certain research and development activities on our behalf, including under agreements with CROs;
- payments under licensing agreements, such as our upfront in-license fee for lotilaner;
- consulting costs and certain allocated payroll and employee-related expenses (including stock-based compensation and salaries) for personnel engaged in research and development functions;
- costs related to compliance with clinical regulatory requirements;
- costs of procuring drug products for use in our preclinical studies and clinical trials; and

- facilities expenses, which include direct and allocated expenses for rent of our laboratory.

We expense both internal and external research and development expenses as incurred or as certain upfront or milestone payments become contractually due to licensors upon achievement of clinical or regulatory events. We recognize external research and development costs based on an evaluation of the progress-to-completion of (i) specific tasks performed or deliverables provided by CROs and CMOs and (ii) patient visits for dosing or other follow-up. To estimate period expense for recognition, we use information provided to us by our service providers and we then apply the corresponding fee schedule.

We track our external research and development expenses on a program-by-program basis, such as fees paid to CROs, CMOs, and research laboratories in connection with our pre-clinical development, process development, manufacturing and clinical development activities. However, we do not currently track employee time on a program-by-program basis. For the years ended December 31, 2022 and 2021, the vast majority of our external and internal research and development expenses are attributable to our TP-03 program for Demodex blepharitis.

We expect our research and development expenses to increase substantially in the future, as we seek to initiate and progress additional clinical trials for our product candidates, including TP-03 for the potential treatment of MGD, TP-04 for the potential treatment of rosacea, and TP-05 for potential Lyme prophylaxis. We expect to complete our clinical programs for these product candidates, and as appropriate, pursue regulatory approval and prepare for the possible commercialization for each.

#### **General and Administrative Expenses**

General and administrative expenses consist of personnel-related costs including payroll, benefits, and stock-based compensation for our executive, finance, sales and marketing, and other administrative functions. Other general and administrative expenses include sales and marketing costs to support our anticipated commercial launch, consulting fees, legal services, rent and other facilities costs, and other general operating expenses not otherwise classified as research and development expenses.

We expect that our general and administrative expenses will increase substantially in the future as a result of expanding our operations, including hiring personnel, preparing for potential commercialization of our product candidates, and additional facility occupancy costs, as well various incremental costs associated with being a public company (including increased legal and accounting fees, regulatory costs associated with maintaining compliance with the rules of the Nasdaq Stock Market and SEC regulations, investor relations activities, directors and officers liability insurance premiums, and other accompanying compliance and governance costs).

#### **Other Income (Expense), Net**

Other income (expense), net primarily consists of (i) interest income earned on our cash, cash equivalents, and marketable securities, (ii) interest expense on the Credit Facility executed in February 2022, and (iii) the change in estimated fair value of the LianBio equity warrants and LianBio common stock we received as part of our China Out-License in March 2021.

#### **Income Tax Benefit (Provision)**

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net operating losses we have incurred in each year, or for our earned research and development tax credits, due to our uncertainty of realizing a benefit from either. As a result of the Tax Cuts and Jobs Act of 2017, net operating losses (for U.S. income tax purposes) generated prior to December 31, 2017 can be carried forward for up to 20 years, while net operating losses generated after December 31, 2017 can be carried forward indefinitely, but are limited to 80% utilization against taxable income. Our California net operating losses will begin to expire in 2037. The federal research and development tax credits begin to expire in 2040 unless previously utilized, and the California credit carryforwards are available indefinitely.

**Results of Operations**

**Comparison of the Years Ended December 31, 2022 and 2021**

The following table summarizes our results of operations for the periods indicated:

	Year Ended December 31,		Change
	2022	2021	
(in thousands)			
<b>Revenues:</b>			
License fees	\$ 23,893	\$ 53,067	\$ (29,174)
Collaboration revenue	1,923	3,960	(2,037)
Total revenues	25,816	57,027	(31,211)
<b>Operating expenses:</b>			
Cost of license fees and collaboration revenue	955	2,075	(1,120)
Research and development	42,624	41,712	912
General and administrative	44,949	25,397	19,552
Total operating expenses	88,528	69,184	19,344
Loss from operations before other income (expense) and income taxes	(62,712)	(12,157)	(50,555)
<b>Other income (expense):</b>			
Interest income	3,499	36	3,463
Interest expense	(2,199)	—	(2,199)
Other income (expense), net	86	(73)	159
Unrealized loss on equity investments	(268)	(591)	323
Change in fair value of equity warrants issued by licensee	(501)	(987)	486
Total other income (expense), net	617	(1,615)	2,232
Loss from operations before income taxes	(62,095)	(13,772)	(48,323)
Benefit (provision) for income taxes	4	(55)	59
Net loss	\$ (62,091)	\$ (13,827)	\$ (48,264)

**License Fees and Collaboration Revenue**

License fees and collaboration revenue was \$25.8 million for the year ended December 31, 2022. This amount represents the contractual milestones achieved or allocated under the China Out-License that have been fully or partially completed by December 31, 2022. These allocated amounts represented the satisfaction of the transfer of license rights to LianBio and the completion of clinical-related performance obligations.

We will recognize additional license fees and collaboration revenue to the extent other events occur, specifically related to (i) milestone achievement of a drug supply agreement execution, (ii) milestone achievement of regulatory events in the China Territory, and (iii) royalties and milestones from our licensee's product sales of TP-03 in the China Territory.

**Cost of License Fees and Collaboration Revenue**

Cost of license fees and collaboration revenue was \$1.0 million for the year ended December 31, 2022. This amount relates to our contractual payment obligations to Elanco, in proportion to our recognized license fee and collaboration revenue in the same period.

**Research and Development Expenses**

Research and development expenses increased by \$0.9 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. The increase was primarily due to (i) \$7.3 million of increased payroll and personnel-related costs (including stock-based compensation), for 22 employee additions year-over-year to drive our product development initiatives, (ii) \$1.0 million of increased regulatory and consulting costs related to our NDA filing for TP-03, (iii) \$0.5 million of licensing milestone expense upon enrollment of the first patient in the first Phase 2a Carpo trial for the treatment of Lyme disease in December 2022, and (iv) \$0.3 million of increased product manufacturing and formulation costs. These increases were partially offset by \$0.8 million of decreased clinical expenses primarily related to the completion of our Saturn-2 trial during the first half of 2022, and other non-recurring contractual costs in the prior year period including (i) a payment in March

2021 through the issuance of 187,500 shares of our common stock (then valued at \$5.5 million to extend the period of our All Human Uses Elanco Agreement), and (ii) a payment of \$2.0 million under the Eye and Derm Elanco Agreement for the commencement of our Saturn-2 trial.

#### **General and Administrative Expenses**

General and administrative expenses increased by \$19.6 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. The increase was primarily due to (i) \$10.4 million of increased payroll and personnel-related costs (including stock-based compensation) for 19 employee additions year-over-year to support our business growth and commercialization efforts, (ii) \$9.7 million of increased commercial and market research costs as we continue our commercial expansion and prepare for the potential launch of TP-03 in the second half of 2023, and (iii) \$0.4 million of increased IT application expenses to support the continued growth and expansion of our corporate infrastructure. These increases were partially offset by \$1.0 million of decreased professional and legal fees. We expect sales and marketing headcount and associated vendor spend to meaningfully increase during 2023 as part of our TP-03 commercial launch-related activities.

#### **Other Income (Expense), Net**

Other income (expense), net increased \$2.2 million for the year ended December 31, 2022. The increase primarily consists of (i) \$3.5 million of increased interest income earned on our cash, cash equivalents and marketable securities, (ii) \$0.5 million change in estimated fair value of the LianBio equity warrants we received as part of our China Out-License in March 2021, and (iii) \$0.3 million change in fair value of the LianBio common stock (after our exercise of the first and second warrant tranches). These increases were partially offset by \$2.2 million of interest expense on the Credit Facility executed in February 2022.

#### **Liquidity and Capital Resources**

##### **Sources of Liquidity**

###### **Overview**

As of December 31, 2022, we had cash, cash equivalents and marketable securities of \$217.0 million. Since our inception, our operations have been substantially financed by cash proceeds of private placements of preferred stock, IPO proceeds from the issuance of common stock, China Out-License consideration, Credit Facility draw, and the Follow-On Public Offering of common stock.

###### **IPO and Follow-On Public Offering**

In connection with our October 2020 IPO, we sold 6,325,000 shares of our common stock (inclusive of the full exercise of the underwriters' option to purchase 825,000 shares of common stock). After deducting underwriting discounts, commissions and other related expenses, our IPO proceeds were \$91.7 million. In May 2022, we completed the Follow-On Public Offering. We also granted the underwriters a 30-day option to purchase up to 840,000 additional shares of common stock at the public offering price, less underwriting discounts and commissions. In June 2022, the underwriters partially exercised their option to purchase an additional 289,832 shares of common stock at the offering price of \$13.50 per share, before underwriting discounts and commissions. After giving effect to the exercise of the underwriters' option, we sold 5,889,832 shares for total gross proceeds of \$79.5 million, before underwriting discounts, commissions and other estimated offering expenses for total net proceeds received of \$74.3 million.

###### **China Out-License**

As of December 31, 2022, we have received \$80.0 million of total proceeds in connection with our China Out-License, inclusive of 2022 milestone receipts of \$25.0 million for the achievement of two development milestones. We expect to receive an additional \$5.0 million during 2023 for the achievement of a development milestone, for cumulative milestone receipts of \$85.0 million through December 2023. The remaining \$120.0 million of available milestones under this arrangement will potentially be received upon future regulatory and sales achievements all within the China Territory.

###### **Credit Facility**

In February 2022, we drew \$20.0 million from our Credit Facility with Hercules and SVB. Capital draws, at our election, are in \$5.0 million increments. This Credit Facility was amended in January 2023. The Credit Facility, as amended,



includes an extended period to draw down the tranche associated with the NDA submission, from March 15, 2023 to March 15, 2024 provided at least \$5 million is drawn on or before March 15, 2023 and at least an additional \$5 million is drawn on or before September 15, 2023. On March 15, 2023 we made a \$5.0 million draw (including SVB's commitment of \$1.25 million) from the \$25.0 million tranche associated with the NDA submission of TP-03. This Credit Facility includes a four-year period of interest-only payments and is extendable for a fifth year to February 2027 maturity, upon our expected achievement of required conditions. We currently have no other financing commitments, such as lines of credit or guarantees.

As of the date of this filing, we have \$130.0 million of remaining tranching availability as follows:

- \$20.0 million upon the NDA submission of TP-03 in September 2022;
- \$35.0 million upon FDA approval of TP-03;
- \$50.0 million upon achievement of certain quarterly revenue thresholds; and
- \$25.0 million available with lender approval.

## **Funding Requirements**

### **Cash Runway**

Our operating expenditures currently consist of research and development costs (including activities within our preclinical, clinical, regulatory, and drug manufacturing initiatives) and general and administrative costs. Our use of cash is impacted by the timing and extent of payments for each of these activities and other business requirements.

We believe that our cash and investments of \$217.0 million as of December 31, 2022 is sufficient to fund our current and planned operations for at least the next twelve months from the date of filing this Annual Report on Form 10-K. These funds, in combination with our expected milestone proceeds through 2025 from our China Out-License of \$20.0 million (\$5 million of which is expected to be received during 2023), and total draws from our Credit Facility of \$60.0 million or less, are anticipated to fully fund our planned requirements for commercial launch, pipeline development, operating expenses, and capital expenditures at least into the second half of 2026. We anticipate having at least \$60.0 million of availability for new draws under our Credit Facility by December 2023 and \$75.0 million of additional tranching availability through December 2024. The Credit Facility requires interest-only debt service payments that are expected to remain through its maturity in February 2027 and its remaining tranches are subject to undrawn expiry in either March 2024 or December 2024 (see *Note 10*).

Our cash runway estimate is predicated on current assumptions for future revenue, operating expenses, and debt availability and may require future adjustments. Accordingly, we may be required to raise additional capital earlier than we currently expect based on our cash requirements and market dynamics.

### **Shelf Registration Statement**

On November 1, 2021, we filed a shelf registration statement on Form S-3 that was declared effective by the SEC on November 5, 2021 (the "Shelf Registration Statement"), which permitted us to offer up to \$300.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination, including in units from time to time. We have approximately \$220 million remaining under our Shelf Registration Statement, after giving effect to the Follow-On Public Offering (but inclusive of the sales agreement prospectus described below). Our Shelf Registration Statement is intended to provide us with additional flexibility to access capital markets for general corporate expenses and acquisitions of complementary products, technologies, or businesses. We completed the Follow-On Public Offering under this Shelf Registration Statement.

Also, as part of this Shelf Registration Statement, we concurrently filed a sales agreement prospectus covering the sale of up to \$100.0 million of our common stock pursuant to an Open Market Sale Agreement<sup>SM</sup> (the "ATM Agreement") with Jefferies LLC. Through the date of this filing, we have not sold any shares of our common stock under the ATM Agreement.

### **Other Liquidity Risks**

To date, we have not generated revenue from any product sales, though we have recognized revenue and cash receipts from our China Out-License. We do not expect to report any product revenue unless and until we (1) complete development of any of our product candidates; (2) obtain applicable regulatory approvals; and then (3) successfully commercialize our product candidates or enter into other collaborative agreements for our product candidates with third parties. We do not know with certainty when, or if, any of these items will ultimately occur.

We expect to incur significant operating losses for the foreseeable future, and for these losses to further increase, as we expand our clinical development programs and as we prepare for the potential commercial launch of TP-03. We may also encounter unforeseen expenses, difficulties, complications, delays and other currently unknown factors that could adversely affect our business.

We may require additional capital to fully develop our product candidates and to execute our business strategy. Our requirements of a future capital raise will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time and availability of our Credit Facility;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of various computerized information systems;
- impact of health epidemics, including COVID-19, on our clinical development or operations; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our 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. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations 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 potential inability to raise capital when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds as required, we may need to delay, reduce, or terminate some or all development programs and clinical trials. We may also be required to sell or license our rights to product candidates in certain territories or indications that we would otherwise prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to address our liquidity needs, 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 and adversely affect our business and financial prospects. See the section of this Annual Report on Form 10-K titled "Risk Factors" for additional risks associated with our substantial capital requirements.

#### Contractual Obligations and Commitments

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods. Such arrangements include those related to the contractual obligations described below:

##### Lease Commitments

Our operating lease commitments reflect payments due for our active lease agreements in Irvine, California, for adjacent office and laboratory suites which expire on January 31, 2024, with a renewal option for a term of three years. As of December 31, 2022, our contractual commitments for our leases were \$0.9 million, which will be paid over the lease term.

##### Purchase Obligations

We enter contracts in the normal course of business with CROs for our clinical trials and CMOs for contract manufacturing activities. As of December 31, 2022, our contractual commitments for such obligations were \$10.8 million. We also enter contracts with contract manufacturers for pre-clinical and clinical drug supply, regulatory consultants and various other vendors in operating our business. These contracts generally provide for termination provisions with notice.

##### Milestone Obligations

Milestone obligations are contingent upon our achievement of specified development, regulatory and sales milestones. Given the unpredictability of the drug development process, and the infeasibility of predicting the success of current and future clinical trials and the timing of achievement (if at all) of sales milestones, these values assume that all development, regulatory, and sales milestones under our Eye and Derm Elanco Agreement and All Human Uses Elanco Agreement are successfully met. Assuming the milestones are met, the total future expected payment value aggregates \$158.0 million.

#### Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (49,030)	\$ 3,748
Investing activities	(144,629)	(586)
Financing activities	93,987	21
Net (decrease) increase in cash and cash equivalents	\$ (99,672)	\$ 3,183

#### Net Cash (Used in) Provided by Operating Activities

Net cash used in operating activities was \$49.0 million for the year ended December 31, 2022, which primarily consisted of our net loss of \$62.1 million partially offset by stock-based compensation of \$13.5 million. In the current year, our cash payments to vendors for our operating activities totaled \$53.4 million and payroll-related cash payments (inclusive of 2021 bonus payouts) totaled \$19.1 million. In addition, we made payments to Elanco of \$1.5 million for future TP-04 and TP-05 licensing milestones (see *Note 8(b)*). These cash payments were partially offset by \$25.0 million of cash received (of the \$25.8 million recognized in revenue during 2022) in connection with the China Out-License transaction.

Net cash provided by operating activities was \$3.7 million for the year ended December 31, 2021, which was primarily attributable to \$55.0 million of cash (of the \$57.0 million recognized in revenue during 2021) in connection with the China Out-License transaction. This cash provided by operating activities was partially offset by cash payments to vendors totaling \$42.5 million for our operating activities and payroll-related cash payments (inclusive of 2020 bonus payouts) totaling \$9.4 million. In addition, we made contractual payments of \$4.5 million to Elanco (see *Note 8(b)*).

#### **Net Cash Used in Investing Activities**

Net cash used in investing activities was \$144.6 million for the year ended December 31, 2022, and primarily relates to \$149.4 million of purchased marketable securities and \$0.5 million of purchased office equipment and leasehold improvements for our laboratory and administrative offices. This cash used in investing activities was partially offset by \$5.3 million of proceeds received from sales of our marketable securities.

Net cash used in investing activities was \$0.6 million for the year ended December 31, 2021, which consisted of leasehold improvements for our laboratory and administrative offices and various purchases of computer hardware/software and office equipment.

#### **Net Cash Provided by Financing Activities**

Net cash provided by financing activities was \$94.0 million for the year ended December 31, 2022 which consisted primarily of (i) \$74.4 million of net proceeds from the issuance of common stock in our Follow-On Public Offering, (ii) \$20.0 million of proceeds from our Credit Facility, partially offset by \$0.9 million of issuance costs, (iii) \$0.5 million of proceeds from our employee stock purchase plan, and (iv) \$0.1 million of proceeds from the exercise of vested employee stock options.

Net cash provided by financing activities was \$21 thousand for the year ended December 31, 2021 which consisted of (i) \$0.2 million of proceeds from our employee stock purchase plan, and (ii) \$0.1 million of proceeds from the exercise of vested employee stock options. These increases in cash were partially offset by payments of \$0.3 million related to the deferred offering costs associated with our Shelf Registration Statement filed on November 1, 2021.

#### **Critical Accounting Policies, Significant Judgments and Use of Estimates**

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as 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 judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the notes to our financial statements also included in this Annual Report on Form 10-K, we believe these critical accounting policies are the most important to understanding and evaluating our reported financial results.

#### **Revenue Recognition for Out-License Arrangements**

##### **Overview**

We currently only have the China Out-License arrangement that allows a licensee to market our TP-03 product (representing functional intellectual property) in certain territories for a certain field of use and for a stated term. The accounting and reporting of revenue for out-license arrangements requires significant judgment for: (a) identification of performance obligations within the contract, (b) the contract's transaction price for allocation to the identified performance obligations (including variable consideration) (c) the stand-alone selling price for each identified performance obligation, and (d) the timing and amount of revenue recognition in each period.

The China Out-License arrangement was analyzed under GAAP to determine whether the promised goods or services are distinct or must be accounted for as part of a combined performance obligation. In making these assessments, we consider factors such as the stage of development of the underlying intellectual property and the capabilities of the customer to develop the intellectual property on their own, and/or whether the required expertise is readily available. If the license is not distinct, the license is combined with other promised goods or services as a combined performance obligation for revenue recognition.

The China Out-License arrangement included the following forms of consideration: (i) non-refundable upfront cash payment, (ii) equity-based consideration, (iii) sales-based royalties, (iv) sales-based threshold milestones, (v) drug supply agreement milestone, (vi) development milestone payments, and (vii) regulatory milestone payments. Revenue is recognized in proportion to the allocated transaction price when (or as) the respective performance obligation is satisfied. We evaluate the



progress related to each milestone at each reporting period and, if necessary, adjusts the probability of achievement and related revenue recognition. The measure of progress, and thereby periods over which revenue is recognized, is subject to estimation by management and may change over the course of the agreement.

#### **Contractual Terms for Receipt of Payments**

A performance obligation is a promise in a contract to transfer a distinct good or service and is the unit of accounting. A contract's transaction price is allocated among each distinct performance obligation based on relative standalone selling price and recognized when, or as, the applicable performance obligation is satisfied.

The contractual terms that establish our right to collect specified amounts from our customers and that require contemporaneous evaluation and documentation under GAAP for the corresponding timing and amount of revenue recognition, are as follows:

(1) **Upfront License Fees:** We determine whether non-refundable license fee consideration is recognized at the time of contract execution (i.e., when the license is transferred to the customer and customer is able to use and benefit from the license) or over the actual (or implied) contractual period of the out-license. We also evaluate whether it has any other requirements to provide substantive services that are inseparable from the performance obligation of the license transfer to determine whether any combined performance obligation is satisfied over time or at a point in time. Upfront payments may require deferral of revenue recognition to a future period until we perform obligations under these arrangements.

(2) **Development Milestones:** We utilize the most likely amount method to estimate the amount of consideration to which it will be entitled for achievement of development milestones as these represent variable consideration. For those payments based on development milestones (e.g., patient dosing in a clinical study or the achievement of statistically significant clinical results), we assess the probability that the milestone will be achieved, including its ability to control the timing or likelihood of achievement, and any associated revenue constraint. Given the high degree of uncertainty around the occurrence of these events, we determined the milestone and other contingent amounts to be constrained until the uncertainty associated with these payments is resolved. At each reporting period, we re-evaluate this associated revenue recognition constraint. Any resulting adjustments are recorded to revenue on a cumulative catch-up basis and reflected in the financial statements in the period of adjustment.

(3) **Regulatory Milestones:** We utilize the most likely amount method to estimate the consideration to which it will be entitled and recognizes revenue in the period regulatory approval occurs (the performance obligation is satisfied) as these represent variable consideration. Amounts constrained as variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. We evaluate whether the milestones are considered probable of being reached and not otherwise constrained. Accordingly, due to the inherent uncertainty of achieving regulatory approval, associated milestones are constrained for revenue recognition until achievement.

(4) **Royalties:** Under the sales-or-usage-based royalty exception we recognize revenue based on the contractual percentage of the licensee's sales of products to its customers at the later of (i) the occurrence of the related product sales or (ii) the date upon which the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any royalty revenue from our out-licensing arrangements.

(5) **Sales Threshold Milestones:** Similar to royalties, applying the sales-or-usage-based royalty exception, we recognize revenue from sales threshold milestones at the later of (i) the period the licensee achieves the one-time annual product sales levels in their territories for which we are contractually entitled to a specified lump-sum receipt, or (ii) the date upon which the performance obligation to which some or all of the milestone has been allocated has been satisfied or partially satisfied. To date, we have not recognized any sales threshold milestone revenue from out-licensing arrangements.

We will re-evaluate an out-license transaction price as determined by us in each reporting period as uncertain events are resolved and other changes in circumstances occur.

#### **Research and Development Expenses**

Research and development costs are expensed as incurred or as certain upfront or milestone payments become contractually due to licensors upon the achievement of clinical or regulatory events. Research and development expenses include internal costs directly attributable to in-development programs, including costs of certain salaries and other employee-related costs (including stock-based compensation), and costs to conduct nonclinical studies, clinical trials and contract manufacturing activities. We accrue for these costs based on factors such as estimates of the work completed and in accordance with agreements established with third-party service providers under the service agreements. As it relates to clinical trials, the

financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized. Our objective is to reflect the appropriate expense in our financial statements by matching those expenses with the period in which the services and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial taking into consideration discussions with applicable personnel and outside service providers. In this manner, our clinical trial accrual is dependent in part upon the timely and accurate reporting of progress and efforts incurred from CROs, contract manufacturers and other third-party vendors. Although we expect our estimates to be materially consistent with actual amounts incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed can vary and may result in our reporting changes in estimates in any particular period. We make significant judgments and estimates in determining the accrued liabilities balance at each reporting period. As actual costs become known, we adjust our accrued liabilities. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

#### **Stock-Based Compensation**

We recognize stock-based compensation expense for equity awards granted to employees, consultants, and members of our Board of Directors. The Black-Scholes pricing model is used to estimate the fair value of stock option awards as of the date of grant. The fair value of restricted stock units is representative of the closing share price preceding the date of grant.

For stock-based awards that vest subject to the satisfaction of a service requirement, the related expense is recognized on a straight-line basis over each award's actual or implied vesting period. For stock-based awards that vest subject to a performance condition, we recognize related expense on an accelerated attribution method, if and when it concludes that it is highly probable that the performance condition will be achieved. At each reporting period, we reassess the probability of the achievement of the performance vesting conditions. As applicable, we reverse previously recognized expense in the same period of the forfeiture of unvested awards.

The measurement of the fair value of stock-based awards and recognition of stock-based compensation expense requires assumptions to be estimated by management that involve inherent uncertainties and the application of management's judgment, including (a) the fair value of our common stock on the date of option grant for all awards granted prior to the IPO (b) the expected term of the stock option until its exercise by the recipient, (c) our assumed stock price volatility through a designated peer group of publicly-traded companies for a period equal to the expected option term, (d) the prevailing risk-free interest rate over the expected term, and (d) any expected dividend payments over the expected term. If any of these assumptions change, our stock-based compensation expense for future grants could materially differ.

*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 estimate the volatility of our common stock on the date of grant based on our designated peer group of publicly-traded companies for a look-back period, as of the date of grant, that corresponds with the expected term of the awarded stock option.

*Expected Dividend Rate* – We have an expected dividend yield of zero because we have never paid cash dividends and do not expect to for the foreseeable future.

*Risk-Free Interest Rate* – We estimate the risk-free interest rate based upon the U.S. Department of the Treasury yields in effect at award grant for a period equaling the expected term of the stock option.

#### **Common Stock Valuations**

Prior to the IPO, given the absence of a public trading market, our Board of Directors, with input from management, considered numerous objective and subjective factors to determine the fair value of its common stock. The factors included: (i) third-party valuations of our common stock; (ii) our stage of development; (iii) the status of research and development efforts; (iv) the rights, preferences and privileges of our preferred stock relative to common stock; (v) our

operating results and financial condition, including our levels of available capital resources; (vi) equity market conditions affecting comparable public companies; (vii) general U.S. market conditions; and (viii) the lack of current marketability of our common stock. The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Subsequent to the IPO, the fair value of our common stock is based on the closing quoted market price of our common stock as reported by the Nasdaq Global Select Market on the date of grant.

#### **Recent Accounting Pronouncements**

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in the notes to which they relate within our financial statements.

#### **Indemnification Agreements**

As permitted under Delaware law and in accordance with our bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. We are also party to indemnification agreements with our officers and directors. We believe the fair value of the indemnification rights and agreements is minimal. Accordingly, we have not recorded any liabilities for these indemnification rights and agreements as of December 31, 2022.

#### **JOBS Act Accounting Election**

The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected to opt out of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted.

We will remain an emerging growth company until the earliest of (1) the last day of our first fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenues of at least \$1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million of the prior June 30th and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

**Item 8. Financial Statements and Supplementary Data**

**TARSUS PHARMACEUTICALS, INC.  
INDEX TO THE FINANCIAL STATEMENTS**

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**Report of Independent Registered Public Accounting Firm**

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

**Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Tarsus Pharmaceuticals, Inc. (the Company) as of December 31, 2022 and 2021, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

**Basis for Opinion**

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

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

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

/s/ Ernst & Young LLP

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

Irvine, California  
March 17, 2023

**TARSUS PHARMACEUTICALS, INC.**  
**BALANCE SHEETS**  
(In thousands, except share and par value amounts)

	December 31,	
	2022	2021
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 71,660	\$ 171,332
Marketable securities	145,366	483
Other receivables	3,582	92
Prepaid expenses	4,767	4,045
Total current assets	225,375	175,952
Property and equipment, net	957	755
Operating lease right-of-use assets	575	1,074
Long-term investments	371	—
Other assets	585	1,126
<b>Total assets</b>	<b>\$ 227,863</b>	<b>\$ 178,907</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable and other accrued liabilities	\$ 9,910	\$ 8,680
Accrued payroll and benefits	5,519	2,798
Total current liabilities	15,429	11,478
Term loan, net	19,434	—
Other long-term liabilities	100	699
<b>Total liabilities</b>	<b>34,963</b>	<b>12,177</b>
<b>Commitments and contingencies (Note 8)</b>		
<b>Stockholders' equity:</b>		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 26,727,458 shares issued and outstanding at December 31, 2022; 20,726,580 shares issued and 20,698,737 outstanding, which excludes 27,840 shares subject to repurchase at December 31, 2021	5	4
Additional paid-in capital	301,732	213,398
Accumulated other comprehensive loss	(74)	—
Accumulated deficit	(108,763)	(46,672)
<b>Total stockholders' equity</b>	<b>192,900</b>	<b>166,730</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 227,863</b>	<b>\$ 178,907</b>

*See accompanying notes to financial statements.*



**TARSUS PHARMACEUTICALS, INC.**  
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	2021
<b>Revenues:</b>		
License fees	\$ 23,893	\$ 53,067
Collaboration revenue	1,923	3,960
Total revenues	25,816	57,027
<b>Operating expenses:</b>		
Cost of license fees and collaboration revenue	955	2,075
Research and development	42,624	41,712
General and administrative	44,949	25,397
Total operating expenses	88,528	69,184
Loss from operations before other income (expense) and income taxes	(62,712)	(12,157)
<b>Other income (expense):</b>		
Interest income	3,499	36
Interest expense	(2,199)	—
Other income (expense), net	86	(73)
Unrealized loss on equity investments	(268)	(591)
Change in fair value of equity warrants issued by licensee	(501)	(987)
Total other income (expense), net	617	(1,615)
Loss from operations before income taxes	(62,095)	(13,772)
Benefit (provision) for income taxes	4	(55)
Net loss	\$ (62,091)	\$ (13,827)
<b>Other comprehensive loss:</b>		
Unrealized loss on marketable securities and cash equivalents	(74)	—
Comprehensive loss	\$ (62,165)	\$ (13,827)
Net loss per share, basic and diluted	\$ (2.52)	\$ (0.67)
Weighted-average shares outstanding, basic and diluted	24,619,700	20,554,086

*See accompanying notes to financial statements.*

TARSUS PHARMACEUTICALS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY  
(In thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
<b>Balance as of December 31, 2020</b>	—	\$ —	20,323,201	\$ 4	\$ 198,821	\$ —	\$ (32,845)	\$ 165,980
Net loss	—	—	—	—	—	—	(13,827)	(13,827)
Recognition of stock-based compensation expense	—	—	—	—	8,455	—	—	8,455
Shares issued as consideration for in-license rights	—	—	187,500	—	5,494	—	—	5,494
Lapse of repurchase obligation for stock option exercises, prior to vesting	—	—	151,535	—	304	—	—	304
Exercise of vested stock options	—	—	24,959	—	103	—	—	103
Shares issued in connection with the employee stock purchase plan	—	—	11,542	—	221	—	—	221
<b>Balance as of December 31, 2021</b>	—	\$ —	20,698,737	\$ 4	\$ 213,398	\$ —	\$ (46,672)	\$ 166,730
Net loss	—	—	—	—	—	—	(62,091)	(62,091)
Recognition of stock-based compensation expense	—	—	—	—	13,460	—	—	13,460
Issuance of common stock upon follow-on public offering, net of issuance costs of \$5,280	—	—	5,889,832	1	74,233	—	—	74,234
Lapse of repurchase obligation for stock option exercises, prior to vesting	—	—	27,840	—	56	—	—	56
Exercise of vested stock options	—	—	40,979	—	123	—	—	123
Issuance of common stock upon the vesting of restricted stock units	—	—	32,914	—	—	—	—	—
Shares issued in connection with the employee stock purchase plan	—	—	37,156	—	462	—	—	462
Other comprehensive loss	—	—	—	—	—	(74)	—	(74)
<b>Balance as of December 31, 2022</b>	—	\$ —	26,727,458	\$ 5	\$ 301,732	\$ (74)	\$ (108,763)	\$ 192,900

See accompanying notes to financial statements.



TARSUS PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS  
(In thousands)

	Year ended December 31,	
	2022	2021
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$ (62,091)	\$ (13,827)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	325	312
Stock-based compensation	13,460	8,455
Accretion of term loan-related costs	309	—
Non-cash lease expense	464	294
Loss on lease termination	—	2
Loss on disposal of property and equipment	—	70
Amortization of discount on available-for-sale debt securities	(1,316)	—
Unrealized loss on equity investment	268	591
Change in fair value of equity warrants issued by licensee	501	987
Unrealized gain from transactions denominated in a foreign currency	1	(2)
Issuance of common stock upon in-license agreement milestone achievement	—	5,494
Changes in operating assets and liabilities:		
Other receivables	(3,490)	(73)
Prepaid expenses	(721)	(2,043)
Other non-current assets	(215)	(2,265)
Accounts payable and other accrued liabilities	821	3,880
Accrued payroll and benefits	2,721	1,758
Other long-term liabilities	(67)	115
Net cash (used in) provided by operating activities	<u>(49,030)</u>	<u>3,748</u>
<b>Cash Flows From Investing Activities:</b>		
Proceeds from sales of marketable securities	5,315	—
Purchases of marketable securities	(149,438)	—
Purchases of property and equipment	(506)	(586)
Net cash used in investing activities	<u>(144,629)</u>	<u>(586)</u>
<b>Cash Flows From Financing Activities:</b>		
Proceeds from issuance of common stock upon follow-on public offering, net of paid issuance costs	74,352	—
Proceeds from term loan	20,000	—
Proceeds from sale of common stock under employee stock purchase plan	462	221
Proceeds from exercise of vested stock options	123	103
Payment of deferred offering costs	(75)	(303)
Payment of term loan issuance costs	(875)	—
Net cash provided by financing activities	<u>93,987</u>	<u>21</u>
<b>Net (decrease) increase in cash and cash equivalents</b>	<u>(99,672)</u>	<u>3,183</u>
<b>Cash and cash equivalents — beginning of year</b>	<u>171,332</u>	<u>168,149</u>
<b>Cash and cash equivalents — end of year</b>	<u>\$ 71,660</u>	<u>\$ 171,332</u>
<b>Supplemental Disclosures Noncash Investing and Financing Activities:</b>		
Interest expense paid in cash	\$ 1,675	\$ —
Additions of property and equipment included within accounts payable and other accrued liabilities	\$ 21	\$ 2
Stock issued for in-license agreements included within research and development expense	\$ —	\$ 5,494
Operating lease right-of-use asset obtained in exchange for operating lease liability	\$ —	\$ 741
Expense of right-of-use asset upon lease termination	\$ —	\$ (38)
Deferred offering costs included in accounts payable and accrued liabilities	\$ —	\$ 60

See accompanying notes to financial statements.

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS  
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

**1. DESCRIPTION OF BUSINESS AND PRESENTATION OF FINANCIAL STATEMENTS**

**Description of Business**

Tarsus Pharmaceuticals, Inc. ("Tarsus" or the "Company") is a biopharmaceutical company focused on the development and commercialization of therapeutics, starting with eye care. The Company's operations currently consist of its preclinical and clinical studies, corporate administration and commercial leadership supporting planned business growth.

**Liquidity**

The Company has a limited operating history, no product sales and has accumulated losses and negative cash flows from operations since inception. The Company has funded its inception-to-date operations through equity capital raises; including the Company's initial public offering in 2020 and the follow-on public offering completed in May 2022 (see *Note 4*), proceeds from an out-license agreement, and a draw on its credit facility. The Company estimates that its existing capital resources will be sufficient to meet projected operating expense requirements for at least 12 months from the issuance date of the Financial Statements that have been prepared on a going-concern basis.

Management expects the Company to continue to incur operating losses for the foreseeable future and may be required to raise additional capital to fund its ongoing operations. However, no assurance can be given as to whether financing will be available on terms acceptable to the Company, or at all. If the Company is unable to raise additional funds as required, it may need to delay, reduce, or terminate some or all of its development programs and clinical trials. The Company may also be required to sell or license its rights to product candidates in certain territories or indications that it would otherwise prefer to develop and commercialize on its own and/or enter into collaborations and other arrangements to address its liquidity needs, which could materially and adversely affect its business and financial prospects, or even its ability to remain a going concern.

**Operating Segment**

To date, the Company has operated, managed and organized its business and financial information on an aggregate basis for the purpose of evaluating financial performance and the allocation of capital and personnel resources. The Company's chief operating decision-maker (CODM), its Chief Executive Officer, reviews its operating results for the purpose of allocating resources and evaluating financial performance. Accordingly, the Company's management determined that it operates one reportable operating segment.

**Emerging Growth Company Status**

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to not take this exemption. As a result, it will adopt new or revised accounting standards on the relevant effective dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND USE OF ESTIMATES**

**(i) Basis of Presentation**

The accompanying Financial Statements have been prepared in conformity with generally accepted accounting principles ("GAAP") in the United States ("U.S.") and with the rules and regulations of the Securities and Exchange Commission ("SEC"). The preparation of financial statements in conformity with GAAP and with the rules and regulations of the SEC requires management to make informed estimates and assumptions that affect the amounts reported in these accompanying Financial Statements and Notes. These estimates and assumptions are based upon historical experience, knowledge of current events and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS  
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

not readily apparent from other sources and involve judgments with respect to numerous factors that are difficult to predict and may materially differ from the amounts ultimately realized and reported due to the inherent uncertainty of any estimate or assumption. Actual results could differ materially from those estimates.

The Company's financial statements as of and for the year ended December 31, 2022 reflect the Company's estimates of the impact of the macroeconomic environment, including the impact of inflation, higher interest rates, foreign exchange rate fluctuations and the COVID-19 pandemic. The duration and the scope of these conditions cannot be predicted; therefore, the extent to which these conditions will directly or indirectly impact the Company's business, results of operations and financial condition, is uncertain. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments and assumptions or a revision of the carrying value of the Company's assets or liabilities as of the issuance date of the accompanying Financial Statements.

The accounting policies and estimates that most significantly impact the presented amounts within these accompanying Financial Statements are further described below:

**(ii) Cash and Cash Equivalents**

Cash and cash equivalents consist of bank deposits and highly liquid investments, including money market fund accounts, that are readily convertible into cash without penalty, with original maturities of three months or less from the purchase date. The carrying amounts reported in the accompanying Balance Sheets for cash and cash equivalents are valued at cost, which approximate their fair value.

**(iii) Marketable Securities and Long-Term Investments**

As of December 31, 2022, marketable securities consist of short-term fixed income investments carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities (see *Note 7*). Management determines the appropriate classification of its investments in fixed income securities at the time of purchase. Available-for-sale securities are classified as current assets on the accompanying Balance Sheets due to their highly liquid nature and availability for use in current operations.

Marketable securities are recorded at fair value with unrealized losses and gains reported as a component of accumulated other comprehensive loss within the accompanying Statements of Stockholders' Equity until realized. The Company periodically evaluates whether declines in fair values of its available-for-sale securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the available-for-sale security until a forecasted recovery occurs. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, as well as interest and dividends, are included in interest income. Realized losses and gains as well as credit losses, if any, on marketable securities identified on a specific identification basis and are included in other income (expense), net on the accompanying Statements of Operations and Comprehensive Loss. The Company evaluated the underlying credit quality and credit ratings of the issuers during the period. To date, the Company has not identified any other than temporary declines in fair value of its investments and no credit losses associated with credit risk have occurred or have been recorded. Interest earned on marketable securities is included in interest income within the accompanying Statement of Operations and Comprehensive Loss.

As of December 31, 2021, marketable securities consisted of holdings of LianBio Ophthalmology Limited ("LianBio") common stock. These shares are classified within long-term investments on the accompanying Balance Sheet as of December 31, 2022, reflecting the intent to hold these shares for at least one year from the balance sheet date, with associated gains or losses reported in other income (expense), net within the accompanying Statements of Operations and Comprehensive Loss for each reported period.

**(iv) Fair Value Measurements**

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous

TARSUS PHARMACEUTICALS, INC.

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(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

- *Level 1:* Quoted prices (unadjusted) in active markets for identical assets or liabilities that are publicly accessible at the measurement date.
- *Level 2:* Observable prices that are based on inputs not quoted on active markets, but that are corroborated by market data. These inputs may include quoted prices for similar assets or liabilities or quoted market prices in markets that are not active to the general public.
- *Level 3:* Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts for financial instruments consisting of cash, cash equivalents, short-term marketable securities, long-term investments, accounts payable and accrued liabilities approximate fair value due to the short maturities for each. The Company's equity warrant holdings disclosed as other assets are carried at fair value based on unobservable market inputs (see *Note 7*).

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. The Company did not have any transfers of assets and liabilities between the levels of the fair value hierarchy during the years presented.

**(v) Property and Equipment, Net**

Property and equipment, net are stated at historical cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets that range from three to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of the remaining lease term or the estimated useful lives of related improvements. The Company evaluates the recoverability of its property and equipment, net whenever events or changes in circumstances of the business indicate that the asset's carrying amount may not be recoverable. Recoverability of these assets is measured by a comparison of the carrying amounts to the sum of the future undiscounted cash flows the assets are expected to generate over the remaining useful lives of the assets. If a long-lived asset fails a recoverability test, the Company measures the amount by which the carrying value of the asset exceeds its fair value. There were no impairments recognized during the years ended December 31, 2022 and 2021.

**(vi) Concentration of Credit Risk and Other Risks and Uncertainties**

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains cash held in deposit at financial institutions in the U.S., including at Silicon Valley Bank ("SVB"). These deposits are insured by the Federal Deposit Insurance Corporation (FDIC) in an amount up to \$250,000 for any depositor, and with respect to SVB are fully insured per recent correspondence from the FDIC. To the extent the Company holds cash deposits in amounts that exceed the FDIC insurance limitation, it may incur a loss in the event of a failure of any of the financial institutions where it maintains deposits. Management believes the Company is not exposed to significant risk due to the financial position of the depository institution, but will continue to monitor regularly and adjust, if needed, to mitigate risk. The Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity. To date, the Company has not experienced any losses associated with this credit risk and continues to believe that this exposure is not significant.

**(vii) Revenue Recognition for Out-License Arrangements**

**Overview**



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The Company currently has no product revenue. Reported revenue in the accompanying Statements of Operations and Comprehensive Loss is associated with one out-license agreement (the "China Out-License") that allows the third-party licensee to market the Company's TP-03 product candidate (representing functional intellectual property) in the People's Republic of China, Hong Kong, Macau, and Taiwan (the "China Territory") - see Note 9. The accounting and reporting of revenue for out-license arrangements requires significant judgment for: (a) identification of the number of performance obligations within the contract, (b) the contract's transaction price for allocation (including variable consideration), (c) the stand-alone selling price for each identified performance obligation, and (d) the timing and amount of revenue recognition in each period.

The China Out-License was analyzed under GAAP to determine whether the promised goods or services are distinct or must be accounted for as part of a combined performance obligation. In making these assessments, the Company considers factors such as the stage of development of the underlying intellectual property and the capabilities of the customer to develop the intellectual property on their own, and/or whether the required expertise is readily available. If the license is not distinct, the license is combined with other promised goods or services as a combined performance obligation for revenue recognition.

The China Out-License arrangement included the following forms of consideration: (i) non-refundable upfront license payment, (ii) equity-based consideration, (iii) sales-based royalties, (iv) sales-based threshold milestones, (v) drug supply agreement milestone, (vi) development milestone payments, and (vii) regulatory milestone payments. Revenue is recognized in proportion to the allocated transaction price when (or as) the respective performance obligation is satisfied. The Company evaluates the progress related to each milestone at each reporting period and, if necessary, adjusts the probability of achievement and related revenue recognition. The measure of progress, and thereby periods over which revenue is recognized, is subject to estimates by management and may change over the course of the agreement.

**Contractual Terms for Receipt of Payments**

A performance obligation is a promise in a contract to transfer a distinct good or service and is the unit of accounting. A contract's transaction price is allocated among each distinct performance obligation based on relative standalone selling price and recognized when, or as, the applicable performance obligation is satisfied.

The contractual terms that establish the Company's right to collect specified amounts from its customers and that require contemporaneous evaluation and documentation under GAAP for the corresponding timing and amount of revenue recognition, are as follows:

(1) **Upfront License Fees:** The Company determines whether non-refundable license fee consideration is recognized at the time of contract execution (i.e., when the license is transferred to the customer and the customer is able to use and benefit from the license) or over the actual (or implied) contractual period of the China Out-License. The Company also evaluates whether it has any other requirements to provide substantive services that are inseparable from the performance obligation of the license transfer to determine whether any combined performance obligation is satisfied over time or at a point in time. Upfront payments may require deferral of revenue recognition to a future period until the Company performs obligations under these arrangements.

(2) **Development Milestones:** The Company utilizes the most likely amount method to estimate the amount of consideration to which it will be entitled for achievement of development milestones as these represent variable consideration. For those payments based on development milestones (e.g., patient dosing in a clinical study or the achievement of statistically significant clinical results), the Company assesses the probability that the milestone will be achieved, including its ability to control the timing or likelihood of achievement, and any associated revenue constraint. Given the high degree of uncertainty around the occurrence of these events, the Company determines the milestone and other contingent amounts to be constrained until the uncertainty associated with these payments is resolved. At each reporting period, the Company re-evaluates this associated revenue recognition constraint. Any resulting adjustments are recorded to revenue on a cumulative catch-up basis, and reflected in the financial statements in the period of adjustment.

(3) **Regulatory Milestones:** The Company utilizes the most likely amount method to estimate the consideration to which it will be entitled and recognizes revenue in the period regulatory approval occurs (the performance obligation is satisfied) as these represent variable consideration. Amounts constrained as variable consideration are included in the

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transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company evaluates whether the milestones are considered probable of being reached and not otherwise constrained. Accordingly, due to the inherent uncertainty of achieving regulatory approval, associated milestones are deemed constrained for revenue recognition until achievement.

(4) **Royalties:** Under the sales-or-usage-based royalty exception the Company recognizes revenue based on the contractual percentage of the licensee's sale of products to its customers at the later of (i) the occurrence of the related product sales or (ii) the date upon which the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue from the China Out-License.

(5) **Sales Threshold Milestones:** Similar to royalties, applying the sales-or-usage-based royalty exception, the Company recognizes revenue from sales threshold milestones at the later of (i) the period the licensee achieves the one-time annual product sales levels in their territories for which the Company is contractually entitled to a specified lump-sum receipt, or (ii) the date upon which the performance obligation to which some or all of the milestone has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any sales threshold milestone revenue from out-licensing arrangements.

The Company re-evaluates the measure of progress to each performance obligation in each reporting period as uncertain events are resolved and other changes in circumstances occur.

**(viii) Research and Development Costs**

Research and development costs are expensed as incurred or as certain upfront or milestone payments become contractually due to licensors upon the achievement of clinical or regulatory events. Research and development expenses include internal costs directly attributable to in-development programs, including costs of certain salaries and other employee-related costs (including stock-based compensation), and costs to conduct nonclinical studies, clinical trials and contract manufacturing activities. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with third-party service providers under the service agreements. As it relates to clinical trials, the financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized. The Company's objective is to reflect the appropriate expense in its financial statements by matching those expenses with the period in which the services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial taking into consideration discussions with applicable personnel and outside service providers. The clinical trial accrual is dependent in part upon the timely and accurate reporting of progress and efforts incurred from CROs, contract manufacturers and other third-party vendors. Although estimates are expected to be materially consistent with actual amounts incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed can vary and may result in changes in estimates in any particular period. The Company makes significant judgments and estimates in determining the accrued liabilities balance at each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. To date, there have been no material differences between estimates of such expenses and the amounts actually incurred.

**(ix) Stock-Based Compensation**

The Company recognizes stock-based compensation expense for equity awards granted to employees, consultants, and members of its Board of Directors. Stock option awards are at an exercise price of not less than 100% of the fair market value of common stock on the respective date of grant. The grant date is the date the terms of the award are formally approved by the Company's Board of Directors or its designee. The Company uses the Black-Scholes option pricing model to estimate the fair value of stock option awards as of the date of grant. The fair value of restricted stock units is representative of the closing market price of the Company's common stock on the date preceding the award grant-date.

Stock awards granted typically have one to four-year service conditions and a contractual term of 10 years. Any performance conditions for vesting are explicitly stated in each award agreement and are associated with clinical, business

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development, or operational milestones. For stock-based awards that vest subject to the satisfaction of a service requirement, the related expense is recognized on a straight-line basis over each award's actual or implied vesting period. For stock-based awards that vest subject to a performance condition, the Company recognizes related expense on an accelerated attribution method, if and when it concludes that it is highly probable that the performance condition will be achieved. At each reporting period, the Company reassesses the probability of the achievement of the performance vesting conditions. As applicable, the Company reverses previously recognized expense for unvested awards in the same period of forfeiture.

The measurement of the fair value of stock option awards and recognition of stock-based compensation expense requires assumptions to be estimated by management that involve inherent uncertainties and the application of management's judgment, including (a) the fair value of the Company's common stock on the date of the option grant for all awards granted prior to the IPO, (b) the expected term of the stock option until its exercise by the recipient, (c) stock price volatility over the expected term, (d) the prevailing risk-free interest rate over the expected term, and (e) expected dividend payments over the expected term.

Management estimates the expected term of awarded stock options utilizing the simplified method for awards since the Company does not yet have sufficient exercise history since its November 2016 corporate formation and also lacks specific historical and implied stock volatility information. Accordingly, management estimates this expected volatility based on a designated peer-group of publicly-traded companies for a look-back period (from the date of grant), that corresponds with the expected term of the awarded stock option. The Company estimates the risk-free interest rate based upon the U.S. Department of the Treasury yield curve in effect at award grant for the time period that corresponds with the expected term of the awarded stock option. The Company's expected dividend yield is zero because it has never paid cash dividends and does not expect to for the foreseeable future. Subsequent to the IPO, the fair value of the Company's common stock is based on the closing quoted market price of its common stock as reported by the Nasdaq Global Select Market on the date of grant.

**(x) Income Taxes**

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recorded based on the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the financial statements, as well as operating losses and tax credit carry forwards using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain due to the Company's historical operating performance and recorded cumulative net losses in prior fiscal periods. A valuation allowance is recorded to reduce deferred tax assets, because based upon a weighting of positive and negative factors, it is more likely than not that these deferred tax assets will not be realized. If/when the Company were to determine that deferred tax assets are realizable, an adjustment to the corresponding valuation allowance would increase the net income in the period that such determination was made.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcomes of examinations by tax authorities in determining the adequacy of its provision for income taxes. The Company continually assesses the likelihood and amount of potential revisions and adjusts the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

Interest and penalties related to unrecognized tax benefits, if any, are recorded as a component of income tax expense.

**(xi) Net Loss per Share**

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Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method and if-converted method as applicable.

The Company's participating securities include unvested common stock awards issued upon early exercise of certain stock options, as early exercised unvested common stock awards have a non-forfeitable right to dividends. The Company's participating securities do not have a contractual obligation to share in the Company's losses, so in periods of net losses, the two-class method of calculating basic and diluted earnings per share is not required. In periods of net income, basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. Also, net income is attributed to both common stockholders and participating security holders, and therefore, net income is allocated to shares of common stock and participating securities, as if all of the earnings for the period had been distributed. Diluted earnings per share under the two-class method is calculated using the more dilutive of the treasury stock or the two-class method.

Due to net losses in all periods presented, all otherwise potentially dilutive securities are antidilutive, and accordingly, the reported basic net loss per share equals diluted net loss per share.

**(xii) Comprehensive Loss**

Comprehensive loss represents (i) net loss for the periods presented, and (ii) unrealized gains or losses on our reported available-for-sale debt securities.

**(xiii) Recently Issued or Effective Accounting Standards**

Recently issued or effective accounting pronouncements that impact, or may have an impact, on the Company's financial statements have been discussed within the footnote to which each relates. Other recent accounting pronouncements not disclosed in these Financial Statements have been determined by the Company's management to have no impact, or an immaterial impact, on its current financial position, results of operations, or cash flows.

**3. BALANCE SHEET ACCOUNT DETAIL**

The composition of selected captions within the accompanying Balance Sheets are summarized below:

**(a) Prepaid Expenses**

Prepaid expenses consists of the following:

	December 31,	
	2022	2021
Prepaid insurance	\$ 1,177	\$ 1,213
Prepaid research and development expenses	757	671
Prepaid computer software fees	444	56
Other prepaid expenses	2,389	2,105
Prepaid expenses	\$ 4,767	\$ 4,045

**(b) Other receivables**

Other receivables consists of the following:



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	December 31,	
	2022	2021
Regulatory fee reimbursement <sup>(1)</sup>	\$ 3,117	\$ —
Interest receivable	178	2
Research and development service receivables	161	—
Payroll tax receivable	90	90
Income tax receivable	36	—
Other receivables	\$ 3,582	\$ 92

<sup>(1)</sup> This amount represents the required FDA filing fee upon the Company's submission of its New Drug Application ("NDA") for TP-03 and was fully refundable based on the Company's status as a qualified "Small Business" as defined in the relevant Federal statute; it was received from the FDA in January 2023.

**(c) Property and Equipment, Net**

Property and equipment, net consists of the following:

	December 31,	
	2022	2021
Furniture and fixtures	\$ 714	\$ 596
Office equipment	197	84
Laboratory equipment	167	167
Leasehold improvements	425	129
Property and equipment, at cost	1,503	976
(Less): Accumulated depreciation and amortization	546	221
Property and equipment, net	\$ 957	\$ 755

Depreciation expense for the years ended December 31, 2022 and 2021 was \$0.3 million and \$0.3 million, respectively.

**(d) Other Assets**

Other assets consists of the following:

	December 31,	
	2022	2021
Equity warrants issued by licensee (Note 7)	\$ 108	\$ 663
Deposits	82	71
Other non-current assets	395	392
Other Assets	\$ 585	\$ 1,126

**(e) Accounts Payable and Other Accrued Liabilities**

Accounts payable and other accrued liabilities consists of the following:

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	December 31,	
	2022	2021
Trade accounts payable and other	\$ 5,269	\$ 2,856
Accrued clinical studies	3,691	4,407
Operating lease liability, current	721	609
Accrued interest, current	215	—
Income taxes payable	14	55
Contract liability	—	697
Employee stock option pre-vesting exercise liability	—	56
Accounts payable and other accrued liabilities	\$ 9,910	\$ 8,680

**(f) Other Long-Term Liabilities**

Other long-term liabilities consists of the following:

	December 31,	
	2022	2021
Operating lease liability, non-current	\$ 52	\$ 585
Lotlaner licensor liability	48	114
Other long-term liabilities	\$ 100	\$ 699

**4. STOCKHOLDERS' EQUITY****2020 and 2016 Equity Incentive Plans**

The Company's Board of Directors and stockholders adopted and approved the Company's 2020 Equity Incentive Plan (the "2020 Plan") in October 2020. The 2020 Plan replaced the Company's 2016 Equity Incentive Plan that was earlier adopted in December 2016 (the "2016 Plan"). However, awards outstanding under the 2016 Plan will continue to be governed by its original terms. The number of shares of the Company's common stock that were initially available for issuance under the 2020 Plan equaled the initial sum of 9,000,000 shares plus 2,432,980 shares that were then available for issuance under the 2016 Plan. The 2020 Plan provides for the following types of awards: incentive and non-statutory stock options, stock appreciation rights, restricted shares, and restricted stock units.

The number of shares of common stock reserved for issuance under the 2020 Plan are increased automatically on the first business day of each fiscal year, commencing in 2021 and ending in 2030, by a number equal to the lesser of: (i) 4% of the shares of common stock outstanding on the last business day of the prior fiscal year; or (ii) the number of shares determined by the Company's Board of Directors. In general, to the extent that any awards under the 2020 Plan are forfeited, terminate, expire or lapse without the issuance of shares, or if the Company reacquires the shares subject to awards granted under the 2020 Plan, those shares will again become available for issuance under the 2020 Plan, as will shares applied to pay the exercise or purchase price of an award or to satisfy tax withholding obligations related to any award.

**Follow-On Public Offering**

In May 2022, the Company completed a follow-on public offering under its Shelf Registration Statement for an initial underwritten sale of 5,600,000 shares of its common stock at a price of \$13.50 per share. The Company also granted the underwriters a 30-day option to purchase up to 840,000 additional shares of its common stock at the public offering price. In June 2022, the underwriters partially exercised this option and the Company's sale of additional 289,832 shares at \$13.50 per share was concurrently completed.

Total gross proceeds from this offering were \$79.5 million (before underwriting discounts, commissions and other estimated offering expenses), resulting in net proceeds of \$74.3 million.

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**Employee Stock Purchase Plan**

Under the terms of the Company's 2020 Employee Stock Purchase Plan, eligible employees can purchase common stock through scheduled payroll deductions. The purchase price is equal to the closing price of the Company's common stock on the first or last day of the offering period (whichever is less), minus a 15% discount. To determine the value of ESPP expense to be recognized during each offering period, the Black-Scholes option-pricing model is used, in combination with the discounted employee price. A participant may purchase a maximum of 3,000 shares of common stock during a six-month offering period, not to exceed \$25,000 at full market value on the offering date during each ESPP year.

Beginning on January 1, 2021, and each January 1st thereafter, pursuant to the terms of the ESPP, the number of common stock available for issuance under the ESPP is automatically increased by an amount equal to the lesser of (i) one percent of the total number of shares of common stock outstanding on the last day of the year, (ii) 2.5 million shares, or (iii) a number determined by the board of directors.

**Common Stock Outstanding and Reserves for Future Issuance**

Common stockholders have one vote for each share of common stock held and are entitled to receive dividends declared by the Company's Board of Directors when legally available for distribution, then-subject to the dividend rights of the holders of preferred stock. For the years ended December 31, 2022 and 2021, no dividends were declared.

The Company's outstanding equity awards and shares reserved for future issuance under its 2020 and 2016 Equity Incentive Plans and 2020 Employee Stock Purchase Plan are summarized below:

	December 31,	
	2022	2021
Common stock awards reserved for future issuance under 2020 and 2016 Equity Incentive Plans	8,346,738	9,266,200
Common stock awards reserved for future issuance under the 2020 Employee Stock Purchase Plan	2,663,319	2,493,488
Stock options issued and outstanding (unvested and vested) under 2020 and 2016 Equity Incentive Plans	3,899,342	2,759,830
Restricted stock units issued and outstanding (unvested) under 2020 Equity Incentive Plan	551,258	17,251
<b>Total shares of common stock reserved</b>	<b>15,460,657</b>	<b>14,536,769</b>

**5. STOCK-BASED COMPENSATION****Stock-Based Compensation Expense**

Stock-based compensation expense was recognized in the accompanying Statements of Operations and Comprehensive Loss for the years ended December 31, 2022 and 2021 as follows:

	Year Ended December 31,	
	2022	2021
Research and development	\$ 3,736	\$ 1,843
General and administrative	9,724	6,612
<b>Total stock-based compensation</b>	<b>\$ 13,460</b>	<b>\$ 8,455</b>

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The fair value of granted stock options was estimated as of the date of grant using the Black-Scholes option-pricing model, based on the following inputs:

	Year Ended December 31,	
	2022	2021
Exercise price	\$12.89 to \$20.64	\$21.40 to \$47.25
Expected term (in years)	6.25	6.25
Risk-free interest rate	1.63% to 4.21%	0.66% to 1.37%
Expected volatility	77.3% to 83.0%	64.8% to 69.4%
Expected dividend yield	—	—
Weighted-average grant-date fair value per stock option	\$ 18.37	\$ 38.06

**Stock Option Activity**

Stock option activity during the years ended December 31, 2022 and 2021 was as follows:

	Number of Shares	Weighted-Average Exercise Price/Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value <sup>(1)</sup>
Outstanding - December 31, 2020	1,836,739	\$ 3.77	9.15	\$ 68,981
Granted	1,005,512	38.06		
Exercised	(24,959)	4.14		
Forfeited	(57,462)	22.18		
Expired	—	—		
Outstanding - December 31, 2021	2,759,830	15.88	8.54	\$ 33,641
Granted	1,227,123	18.37		
Exercised	(40,979)	3.01		
Forfeited	(46,632)	24.60		
Expired	—	—		
Outstanding - December 31, 2022	3,899,342	\$ 16.69	8.07	\$ 19,196
Vested - December 31, 2022	1,669,139	\$ 13.43	7.32	\$ 13,706
Unvested - December 31, 2022	2,223,536	\$ 19.12	8.63	\$ 5,490

(1) Represents the total difference between the stock price fair value as of December 31, 2022 and the stock option exercise price, multiplied by the number of in-the-money options as of December 31, 2022. The amount of any intrinsic value will change in relation to any increases or decreases in the then-determined fair value of the Company's common stock.

The total grant-date fair value of options that vested during the years ended December 31, 2022 and 2021 was \$13.7 million and \$16.3 million, respectively.

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For the year ended December 31, 2022, the Company recorded stock-based compensation expense for stock options of \$10.7 million. As of December 31, 2022, there was unrecognized compensation expense of \$25.5 million related to unvested stock options, which the Company expects to recognize over a weighted average period of 2.3 years.

**Restricted Stock Unit Activity**

Restricted stock unit activity during the year ended December 31, 2022 was as follows:

	Number of Shares	Weighted Average Value per Share
Outstanding - December 31, 2021	17,251	\$ 27.53
Granted	573,009	17.87
Vested	(32,914)	24.17
Forfeited	(6,088)	19.40
Outstanding - December 31, 2022	551,258	\$ 17.78

For the year ended December 31, 2022, the Company recorded stock-based compensation expense for restricted stock units of \$2.5 million. As of December 31, 2022, there was approximately \$8.0 million of unrecorded expense that will be recognized over a weighted average period of 3.0 years.

**6. NET LOSS PER SHARE**

The following table sets forth the computation of basic and diluted net loss per share:

	Year Ended December 31,	
	2022	2021
Net loss	\$ (62,091)	\$ (13,827)
Weighted-average shares—basic and diluted	24,619,700	20,554,086
Net loss per share—basic and diluted	\$ (2.52)	\$ (0.67)

The following outstanding and potentially dilutive securities were excluded from the calculation of diluted net loss per share because their impact under the treasury stock method and if-converted method would have been anti-dilutive for each period presented:

	Year Ended December 31,	
	2022	2021
Stock options, unexercised—vested and unvested	3,899,342	2,759,830
Restricted stock units—unvested	551,258	17,251
Stock options exercised prior to vesting—remaining unvested	—	27,840
Total	4,450,600	2,804,921

**7. FAIR VALUE MEASUREMENTS**

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type are presented in the following table (see Note 2(iv)):

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	Year Ended December 31, 2022			
	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 64,685	\$ —	\$ —	\$ 64,685
U.S. Treasury securities	69,644	—	—	69,644
Commercial paper	—	60,355	—	60,355
Corporate debt securities	—	11,521	—	11,521
Government-related debt securities	—	10,821	—	10,821
Common stock in LianBio	371	—	—	371
Equity warrants (for LianBio shares)	—	—	108	108
Total assets measured at fair value	\$ 134,700	\$ 82,697	\$ 108	\$ 217,505

	Year Ended December 31, 2021			
	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 171,332	\$ —	\$ —	\$ 171,332
Common stock in LianBio	483	—	—	483
Equity warrants (for LianBio shares)	—	—	663	663
Total assets measured at fair value	\$ 171,815	\$ —	\$ 663	\$ 172,478

**Money Market Funds and U.S. Treasury Securities**

Money market funds and U.S. Treasury securities are highly liquid investments and are actively traded with readily-available market prices that are publicly observable and independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

**Commercial Paper, Corporate Debt Securities, and Government-related Debt Securities**

Commercial paper, corporate debt securities and government-related debt securities were valued using Level 2 inputs that utilized industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. The Company reviews trading activity and pricing for these investments as of each measurement date.

**LianBio Common Stock and Equity Warrants**

In March 2021, contemporaneous with the China Out-License transaction (see *Note 9*), the Company and LianBio (a pharmaceutical company focused on the Greater China and other Asian markets; NASDAQ: LIAN), executed a warrant agreement for the Company to purchase, in three tranches, common shares in LianBio. The first two tranches are vested and exercised as of December 31, 2022 and the third warrant tranche will vest upon the achievement of a regulatory event; each has an exercise price at common stock par value.

In June 2021, one of these three warrant tranches was vested and then-converted to 78,373 shares of LianBio common stock, and recognized at fair value within marketable securities as of December 31, 2021, and within long-term investments on the accompanying Balance Sheets as of December 31, 2022. In May 2022, the second warrant tranche was vested and in December 2022, it was exercised and converted into 78,373 shares of LianBio common stock as recognized at fair value within long-term investments on the Balance Sheets as of December 31, 2022. LianBio common stock is classified within Level 1 of the fair value hierarchy, given its publicly reported price on the NASDAQ Global Market.

The third warrant tranche remains classified as Level 3 in the fair value hierarchy and is presented within other assets on the accompanying Balance Sheets as of December 31, 2022 and 2021 (see *Note 3(d)*). The most significant assumptions used in the option pricing valuation model as of each balance sheet date to determine its fair value included



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observable and unobservable inputs: LianBio common stock volatility (based on the historical volatility of similar companies), the probability of regulatory milestone achievement for vesting, and the application of an assumed discount rate.

The estimated fair value of the equity warrant will be remeasured each reporting period with adjustments reported within other income (expense), net on the accompanying Statements of Operations and Comprehensive Loss, until exercised or expired, and is valued in the accompanying Financial Statements as follows:

	Value of equity warrants (see Note 3(d))	
<b>Fair value as of December 31, 2021</b>	\$	663
Remeasurement of equity warrants		(501)
Recognition of equity warrants		103
Exercise of the second tranche of equity warrants into LianBio common stock		(157)
<b>Fair value as of December 31, 2022</b>	\$	108

	Value of equity warrants (see Note 3(d))	
<b>Fair value as of December 31, 2020</b>	\$	—
Initial fair value estimate of equity warrants		1,233
Recognition of equity warrants		1,491
Remeasurement of equity warrants		(987)
Exercise of the first tranche of equity warrants into LianBio common stock		(1,074)
<b>Fair value as of December 31, 2021</b>	\$	663

The fair value and amortized cost of cash and cash equivalents and available-for-sale investments by major security type are presented in the following table:

	December 31, 2022			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
<b>Cash equivalents:</b>				
Money market funds	\$ 64,685	\$ —	\$ —	\$ 64,685
Government-related securities	4,978	—	—	4,978
Commercial paper	1,997	—	—	1,997
Total cash equivalents	\$ 71,660	\$ —	\$ —	\$ 71,660
<b>Marketable securities:</b>				
U.S. Treasury securities	\$ 69,720	\$ 5	\$ (81)	\$ 69,644
Commercial paper	58,358	—	—	58,358
Corporate debt securities	11,524	8	(11)	11,521
Government-related securities	5,838	5	—	5,843
Total marketable securities	\$ 145,440	\$ 18	\$ (92)	\$ 145,366
<b>Long-term investments:</b>				
Common stock in LianBio	639	—	(268)	371
Total long-term investments	\$ 639	\$ —	\$ (268)	\$ 371

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	December 31, 2021			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
<b>Cash equivalents:</b>				
Money market funds	171,332	—	—	171,332
Total cash equivalents	\$ 171,332	\$ —	\$ —	\$ 171,332
<b>Marketable securities:</b>				
Common stock in LianBio	1,074	—	(591)	483
Total marketable securities	\$ 1,074	\$ —	\$ (591)	\$ 483

As of December 31, 2022, substantially all available-for-sale debt securities have a maturity of 12 months or less. Three securities have a contractual maturity between one and five years, with an estimated fair market value of \$4.6 million and amortized cost of \$4.6 million. All available-for-sale debt securities have gross unrealized losses in a continuous loss position for less than one year. The Company did not recognize any other-than-temporary impairment losses on these securities.

**8. COMMITMENTS & CONTINGENCIES**

**(a) Operating Leases**

In the ordinary course of business, the Company enters into lease agreements with unaffiliated third parties for its facilities and office equipment. As of December 31, 2022, the Company had four active leases for adjacent office and laboratory suites in Irvine, California.

Right-of-Use assets (“ROU assets”) represent the Company’s right to control an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the initial non-cancelable lease term, unless there is a renewal option that is reasonably certain to be exercised. The Company uses its incremental borrowing rate at the lease commencement date in determining the discount rate utilized to present value the future minimum lease payments since an implicit interest rate in each at-market lease agreement was not determinable. The Company has lease agreements with both lease and non-lease components, which are accounted for as a single component for all asset classes.

The Company’s variable lease costs, consisting primarily of real estate taxes, insurance costs, and common area maintenance, are expensed as incurred and excluded from the reported ROU asset and lease liability amounts presented in the accompanying Balance Sheets. Rent expense is allocated to research and development and general and administrative expenses in the accompanying Statements of Operations and Comprehensive Loss. The below table summarizes the components of total lease expense:

	Year Ended December 31,	
	2022	2021
Operating lease expense	\$ 569	\$ 385
Variable lease expense	244	144
Short-term lease expense (lease with 12-month term or less)	—	116
Total lease expense	\$ 813	\$ 645

As of December 31, 2022, the Company’s facility leases had a weighted average remaining lease term of 1.1 years and a weighted-average incremental borrowing rate of 10%.

The below table summarizes the (i) minimum lease payments over the next five years and thereafter, (ii) lease arrangement imputed interest, and (iii) present value of future lease payments:



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Operating Leases - Future Payments	December 31, 2022	
2023	\$	874
2024		61
2025		—
2026		—
2027		—
Total future lease payments, undiscounted	\$	935
(Less): Imputed interest		(46)
Present value of operating lease payments <sup>(1)</sup>	\$	889

<sup>(1)</sup>This amount includes the future lease commitments related to a lease amendment executed as of December 31, 2022, that commences in the first quarter of 2023.

**(b) In-License Agreements for Lotilaner****January 2019 Agreement for Skin and Eye Disease or Conditions in Humans**

In January 2019, the Company entered into a license agreement with Elanco Tiergesundheit AG ("Elanco") for exclusive worldwide rights to certain intellectual property for the development and commercialization of lotilaner in the treatment or cure of any eye or skin disease or condition in humans, as amended in June 2022 (the "Eye and Derm Elanco Agreement"). The Company has sole financial responsibility for related development, regulatory, and commercialization activities.

The Company paid \$1.0 million upfront upon execution of the Eye and Derm Elanco Agreement in January 2019, and also paid a required \$1.0 million clinical milestone in September 2020, associated with the first two U.S. pivotal trials for the treatment of Demodex blepharitis. The Company paid an additional \$2.0 million for its second pivotal trial milestone in April 2021, which was recorded in research and development expense in the accompanying Statements of Operations and Comprehensive Loss for the year ended December 31, 2021.

In June 2022, the Company made a contractual prepayment of \$1.5 million that can be applied towards any milestones that become due under the Eye and Derm Elanco Agreement and/or the Company's in-license agreement with Elanco, granting it a worldwide license to certain intellectual property for the development and commercialization of lotilaner for the treatment, palliation, prevention, or cure of "all other" diseases and conditions in humans (i.e., beyond that of the eye or skin), as amended in June 2022 (the "All Human Uses Elanco Agreement").

As part of the China Out-License, the Company made a required contractual payment in the amount of \$2.5 million to Elanco following the receipt of \$25 million of proceeds from LianBio during the second quarter of 2021. During the fourth quarter of 2022, the Company recognized \$0.4 million of cost of license fees and collaboration revenue upon receipt of \$10 million of cash proceeds from LianBio for the achievement of a clinical development milestone, which was applied against the \$1.5 million prepayment.

As of December 31, 2022, the Company is obligated to make further cash payments to Elanco of \$3.0 million under the Eye and Derm Elanco Agreement (that can be offset against any remaining prepaid amounts) upon achievement of certain clinical milestones in the treatment of human skin diseases using lotilaner and a maximum of \$79.0 million for various commercial and sales threshold milestones for the treatment of human skin diseases and the treatment of any type of blepharitis in humans using lotilaner. In addition, the Company will be obligated to pay tiered contractual royalties to Elanco in the mid to high single digits of its net sales. If the Company receives certain types of payments from its sublicensees, it will be obligated to pay Elanco a variable percentage in the low to mid double-digits of such proceeds, except for territories in which it has achieved applicable regulatory approval.

**September 2020 Agreement for All Other Diseases or Conditions in Humans**

In September 2020, the Company executed an All Human Uses Elanco Agreement with Elanco and concurrently issued Elanco 222,460 shares of its common stock with an estimated fair value of \$3.1 million (\$14.0003 per share, approximating the issuance price of the Company's Series C preferred stock in September 2020).

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The Company is required to make cash payments to Elanco under the All Human Uses Elanco Agreement upon the achievement of various clinical milestones up to an aggregate maximum of \$4.0 million, and various commercial and sales threshold milestones up to an aggregate maximum of \$77.0 million. In addition, the Company will be obligated to pay contractual royalties to Elanco in the single digits of its net product sales. If the Company receives certain types of payments from its sublicensees, it will also be obligated to pay Elanco a variable percentage in the low to mid double-digits of such proceeds, except for territories in which it achieved applicable regulatory approval prior to sublicense execution.

In March 2021, the Company entered into the China Out-License agreement with LianBio, that required it to grant Elanco an additional fixed 187,500 shares of the Company's common stock that otherwise would have been issuable no later than the 18-month anniversary of the All Human Uses Elanco Agreement for continued license exclusivity. These issued shares were valued at \$5.5 million, based on the Company's closing stock price of \$29.30 per share on the date this issuance became contractually required and is recognized within research and development expense within the accompanying Statements of Operations and Comprehensive Loss for the year ended December 31, 2021.

In December 2022, a clinical milestone was triggered to Elanco under the All Human Uses Elanco Agreement upon enrollment of the first patient in the Phase 2a Carpo trial, for the treatment of Lyme disease. The related milestone expense of \$0.5 million was applied against the \$1.5 million prepayment and included within research and development expense on the accompanying Statements of Operations and Comprehensive Loss for the year ended December 31, 2022.

**(c) Employment Agreements**

The Company has entered into employment agreements with eight of its executive officers. These agreements provide for the payment of certain benefits upon separation of employment under specified circumstances, such as termination without cause, or termination in connection with a change in control event.

**(d) Consulting Agreements**

The Company has a preexisting consulting agreement with a board member that was appointed in December 2021. This consulting agreement provides for annual cash compensation of approximately \$0.2 million and option grants to purchase 45,134 shares of the Company's common stock, with exercise prices ranging from \$2.01 to \$34.72 per share. This consulting agreement may be terminated by either party with ten days notice and contains standard confidentiality, indemnification, and intellectual property assignment provisions in favor of the Company.

**(e) Litigation Contingencies**

From time to time, the Company may be subject to various litigation and related matters arising in the ordinary course of business. The Company is currently not aware of any such matters where there is at least a reasonable probability that a material loss, if any, has been or will be incurred for financial statement recognition.

**(f) Indemnities and Guarantees**

The Company has certain indemnity commitments, under which it may be required to make payments to its officers and directors in relation to certain transactions to the maximum extent permitted under applicable laws. The duration of these indemnities vary, and in certain cases, are indefinite and do not provide for any limitation of maximum payments. The Company has not been obligated to make any such payments to date and no liabilities have been recorded for this contingency in the accompanying Balance Sheets.

**9. OUT-LICENSE AGREEMENT**

*Out-License of TP-03 Commercial Rights in Greater China in March 2021*

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On March 26, 2021, the Company entered into The China Out-License agreement with LianBio for its exclusive development and commercialization rights of TP-03 (lotilaner ophthalmic solution, 0.25%) in the China Territory, as defined in the agreement, for the treatment of Demodex blepharitis and Meibomian Gland Disease. LianBio is contractually responsible for all clinical development and commercialization activities and costs within the China Territory.

Through December 31, 2022, the Company received payments from LianBio totaling \$80.0 million comprised of an upfront payment of \$15.0 million and \$65.0 million for the achievement of specified milestone events. In February 2023, a development milestone was triggered resulting in expected cash proceeds of \$2.5 million.

The Company is eligible to receive further consideration from LianBio upon the achievement of additional TP-03 events, including (i) additional development milestone payments of up to an aggregate of \$25.0 million (includes \$2.5 million for a milestone triggered in February 2023), (ii) China-based TP-03 sales threshold milestone payments of up to an aggregate of \$100.0 million, (iii) tiered low-to-high-teen royalties for China Territory TP-03 product sales, and (iv) vesting of a LianBio equity warrant upon certain regulatory milestones.

Revenue recognized in the accompanying Statements of Operations and Comprehensive Loss relates to the satisfaction of performance obligations including (i) the transfer of TP-03 license rights in the China Territory to LianBio and (ii) the completion of U.S. clinical activities and then providing LianBio with the related data to supplement its local pivotal trial package for TP-03 in the treatment of Demodex blepharitis.

#### 10. CREDIT FACILITY AGREEMENT

On February 2, 2022, the Company executed the Credit Facility with Hercules Capital, Inc. ("Hercules") and SVB that expires on February 2, 2027. Concurrent with the execution of the Credit Facility, the Company made a \$20.0 million draw.

On January 5, 2023, the Company entered into an amendment to the loan and security agreement (the "First Amendment"). The First Amendment set a maximum interest rate, and updated the terms of prepayment under the Credit Facility and other certain specific conditions, including an extended period for the Company to draw down the \$25.0 million tranche associated with the NDA submission, from March 15, 2023 to March 15, 2024, provided at least \$5.0 million is drawn on or before March 15, 2023 and at least an additional \$5 million is drawn on or before September 15, 2023. The Company did not incur any lender fees as part of this First Amendment.

As of December 31, 2022, the Credit Facility provides for a remaining aggregate principal amount of up to \$135.0 million with tranching availability as follows: \$25.0 million related to the New Drug Application ("NDA") submission with the FDA for TP-03, \$35.0 million upon FDA approval of TP-03, \$50.0 million upon achievement of product net revenue thresholds, and \$25.0 million upon lender approval. On March 15, 2023, the Company made a \$5.0 million draw (including SVB's commitment of \$1.25 million) from the \$25.0 million tranche that became available upon submission of the NDA.

Each of these tranches may be drawn down in \$5.0 million increments at the Company's election. The Credit Facility requires interest-only payments through February 1, 2026, followed by 12 months of principal amortization, unless extended for one year to its maturity, upon meeting certain contractual conditions. All unpaid amounts under the Credit Facility become due on its February 2, 2027 expiry.

Under the First Amendment, the outstanding principal draws accrue interest at a floating interest rate per annum equal to the greater of either (i) The Wall Street Journal prime rate plus 4.45% with an aggregate cap of 11.45% or (ii) 8.45%. At the execution date of the Credit Facility, the Wall Street Journal prime rate was 3.25% and further increased during 2022, reaching 7.50% as of December 31, 2022.

The Company is required to pay a specified fee upon the earlier of (i) February 2, 2027 or (ii) the date the Company prepays, in full or in part, the outstanding principal balance of the Credit Facility ("End of Term Charge"). The current End of Term Charge of \$1.0 million was derived at the execution of the Credit Facility by multiplying 4.75% by the \$20.0 million drawn at closing and is accreted to interest expense through maturity.

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On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver, and SVB was subsequently transferred into a new entity, Silicon Valley Bridge Bank, N.A. On March 12, 2023, the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception. Such parties also announced, among other items, that Silicon Valley Bridge Bank has assumed the obligations and commitments of former SVB, commitments to advance under existing credit agreements will be honored in accordance with and pursuant to the terms of such credit agreements and any other duties or roles under existing credit agreements will be performed by Silicon Valley Bridge Bank in accordance with and pursuant to the terms of such credit facilities.

As of December 31, 2022, the carrying value of the Credit Facility (reported as term loan, net on the accompanying Balance Sheets) consisted of \$20.0 million principal outstanding less legal and administrative issuance costs of approximately \$0.9 million that were recorded as a debt discount to the term loan, net and will continue to be accreted to interest expense using the effective interest method during its term. As of December 31, 2021 the Company had no outstanding debt.

As of December 31, 2022, the effective interest rate for the full term of the Credit Facility was 13.61%. During the year ended December 31, 2022, the Company recognized interest expense on the accompanying Statement of Operations and Comprehensive Loss in connection with the Credit Facility as follows:

	Year Ended December 31, 2022	
Interest expense for term loan	\$	1,890
Accretion of end of term charge		174
Amortization of debt issuance costs		135
Total interest expense related to term loan	\$	2,199

The principal balance of this Credit Facility and related accretion and amortization as of December 31, 2022 is reported on a combined basis as term loan, net on the accompanying Balance Sheet as follows:

	December 31, 2022	
Term loan, gross	\$	20,000
Debt issuance costs		(875)
Accretion of end of term charge		174
Accumulated amortization of debt issuance costs		135
Term loan, net		19,434

11. INCOME TAXES

The components of loss from operations before provision for income taxes were as follows:

	Year Ended December 31,	
	2022	2021
United States	\$ (62,095)	\$ (13,772)
Total	\$ (62,095)	\$ (13,772)

The provision for income taxes from operations were as follows:

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	Year Ended December 31,	
	2022	2021
Current:		
Federal	\$ (4)	\$ 42
State	—	13
	\$ (4)	\$ 55
Deferred:		
Federal	—	—
State	—	—
	—	—
Total income tax (benefit) provision	\$ (4)	\$ 55

A reconciliation of income taxes was computed by applying the federal statutory income tax rate in each period to the pretax loss for the years ended December 31, 2022 and 2021, and adjusted for certain classes of transactions, as summarized below:

	Year Ended December 31,	
	2022	2021
Expected tax benefit at statutory rate	\$ (13,040)	\$ (2,891)
State income tax, net of federal benefit	(212)	(92)
Permanent items	(22)	(12)
Stock-based compensation	606	760
Executive compensation	988	—
Research and development credits	(1,753)	(2,408)
Change in fair value of equity warrants and equity securities	91	331
Other	212	(50)
Change in valuation allowance	13,126	4,417
Income tax (benefit) provision	\$ (4)	\$ 55

Significant components of the deferred tax assets and liabilities were as follows:



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	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carry forwards	\$ 6,679	\$ 4,934
Research and development credit carryforwards	4,723	2,969
Capitalized research and development	7,634	—
Intangible assets	2,970	2,984
Stock-based compensation	2,119	1,136
Other, net	1,199	712
Total deferred tax assets before valuation allowance	25,324	12,735
Less: valuation allowance	(25,201)	(12,059)
Total deferred tax assets	\$ 123	\$ 676
Deferred tax liabilities, net:		
Operating lease right-of-use assets	(123)	(234)
Deferred revenue	—	(442)
Net deferred tax asset	\$ —	\$ —

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company maintains a valuation allowance against its net deferred tax assets due to the uncertainty that such assets will be realized and evaluates the recoverability of its deferred tax assets on at least an annual basis. The Company has determined that its deferred tax assets, with the exception of amounts supported by the reversal of taxable temporary differences, are not realizable. Consequently, the Company has recorded a valuation allowance on deferred tax assets of \$25.2 million and \$12.1 million at December 31, 2022 and 2021, respectively.

At December 31, 2022, the Company has federal and state net operating loss carryforwards of approximately \$31.1 million and \$25.9 million, respectively. As a result of the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), for U.S. income tax purposes, net operating losses generated prior to December 31, 2017 can be carried forward for up to 20 years, while net operating losses generated after December 31, 2017 can be carried forward indefinitely, but are limited to 80% utilization against taxable income. The Company's total federal net operating loss of \$31.1 million will not expire but will only be able to be offset 80% of future taxable income within each year. The other state net operating losses will begin to expire in 2037. At December 31, 2022, the Company had federal and other state research and development tax credits of \$4.7 million and \$1.6 million, respectively. The federal research and development tax credits begin to expire in 2040 unless previously utilized, and the other state credit carryforwards begin to expire in 2037.

The Internal Revenue Code ("IRC") Sections 382 and 383 limit annual use of NOL and research and development credit carryforwards in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not yet completed an ownership change analysis. If a requisite ownership change occurs, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

Uncertain tax positions are evaluated based upon the facts and circumstances that exist at each reporting period. Subsequent changes in judgement based upon new information may lead to changes in recognition, derecognition, and measurement. Adjustment may result, for example, upon resolution of an issue with the taxing authorities or expiration of a statute of limitations barring an assessment for an issue. The Company recognizes a tax benefit from an uncertain tax position when it is more-likely-than-not that it will be sustained upon examination by tax authorities. As of December 31, 2022, the Company had gross unrecognized tax benefits of \$3.4 million, none of which would affect the effective tax rate if recognized. The Company does not anticipate any significant changes in its unrecognized tax benefits over the next 12 months. The Company's policy is to recognize the interest expense and/or penalties related to income tax matters as a component of income tax expense. The Company had no accrual for interest or penalties on the accompanying Balance Sheets at December 31, 2022.

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and has not recognized interest and/or penalties on the accompanying Statements of Operations for the years ended December 31, 2022 or 2021.

The following table summarizes the changes to the gross unrecognized tax benefits:

	Year Ended December 31,	
	2022	2021
Balance at beginning of year	\$ 3,045	\$ 488
Additions related to current year positions	349	658
Additions related to prior year positions	—	1,899
Decreases related to prior year positions	(1)	—
Balance at end of year	\$ 3,393	\$ 3,045

The Company is subject to taxation in the U.S. Federal jurisdiction and various states. All tax years from inception are subject to examination by federal and state tax authorities. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. No interest or penalties related to income tax matters have been incurred at December 31, 2022 and 2021 and the years then ended. Further, the Company is not currently under examination by any federal, state, or local tax authority.



**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures*****Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures***

We maintain a system of disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is processed, recorded, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. These disclosure controls and procedures include, among other processes, controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), as appropriate, to allow for timely decisions regarding required disclosure.

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) under the Exchange Act) as of December 31, 2022. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2022, the Company's disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

***Management's Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). We maintain internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this assessment, our management concluded that our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2022.

***Changes in Internal Control over Financial Reporting***

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

***Inherent Limitations on Effectiveness of Controls***

Our management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**Item 9B. Other Information.**

None.

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

Not applicable.

**Part III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after December 31, 2022 (the "Proxy Statement"), and is incorporated in this Annual Report on Form 10-K by reference.

**Item 11. Executive Compensation**

The information required by this item will be contained in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be contained in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be contained in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

**Item 14. Principal Accountant Fees and Services**

The information required by this item will be contained in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

**Part IV**

**Item 15. Exhibits, Financial Statement Schedules**

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

(1) Financial Statements (included in Part II of this Annual Report on Form 10-K):

- Report of Independent Registered Public Accounting Firm
- Balance Sheets
- Statements of Operations and Comprehensive Loss
- Statements of Stockholder's Equity
- Statements of Cash Flows
- Notes to Financial Statements

(2) Financial Statement Schedules:

All financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements

(b) The following exhibits are included herein or incorporated herein by reference:

**INDEX TO EXHIBITS**

Exhibit Number	Description	Form	File No.	Incorporated by Reference		Filed Herewith
				Exhibit	Filing Date	
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Registrant.</a>	B-K	001-39614	3.1	October 20, 2020	
3.2	<a href="#">Amended and Restated Bylaws of Registrant.</a>	B-K	001-39614	3.2	October 20, 2020	
4.1	<a href="#">Form of Registrant's common stock certificate.</a>	S-1/A	333-249076	4.1	October 9, 2020	
4.2	<a href="#">Description of the Registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934.</a>	10-K	001-39614	4.2	March 14, 2022	
4.3	<a href="#">Amended and Restated Investors' Rights Agreement, dated September 24, 2020, by and among the Registrant and the other parties thereto.</a>	S-1/A	333-249076	4.2	October 9, 2020	
10.1#	<a href="#">Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.</a>	S-1/A	333-249076	10.1	October 9, 2020	
10.2#	<a href="#">Tarsus Pharmaceuticals, Inc. 2016 Stock Plan, as amended and forms of agreements thereunder.</a>	S-1	333-249076	10.2	September 25, 2020	
10.3#	<a href="#">Tarsus Pharmaceuticals, Inc. 2020 Equity Incentive Plan and form of agreements thereunder.</a>	S-8	333-249571	99.2	October 20, 2020	
10.4#	<a href="#">Tarsus Pharmaceuticals, Inc. 2020 Employee Stock Purchase Plan.</a>	S-8	333-249571	99.3	October 20, 2020	
10.5#	<a href="#">Amended and Restated Offer Letter, dated October 8, 2020, between the Registrant and Bobak Azamian, M.D., Ph.D.</a>	S-1/A	333-249076	10.5	October 9, 2020	
10.6#	<a href="#">Offer Letter, dated March 15, 2020, between the Registrant and Leo M. Greenstein.</a>	S-1	333-249076	10.6	September 25, 2020	
10.7#	<a href="#">Offer Letter, dated June 4, 2020, between the Registrant and Seshadri Neervannan, Ph.D.</a>	S-1	333-249076	10.7	September 25, 2020	
10.8#	<a href="#">Offer Letter, dated October 29, 2018, between the Registrant and Mark Holdbrook.</a>	S-1	333-249076	10.8	September 25, 2020	
10.9#	<a href="#">Offer Letter, dated June 22, 2020, between the Registrant and Aziz Motiwala.</a>	S-1	333-249076	10.9	September 25, 2020	
10.10	<a href="#">Office Lease, dated May 28, 2020, between the Registrant and Discovery Business Center LLC.</a>	S-1	333-249076	10.13	September 25, 2020	
10.11#*	<a href="#">Sublease Agreement, dated May 29, 2020, between the Registrant and Avent, Inc., as amended by First Amendment to Sublease Agreement, dated July 30, 2020, between the Registrant and Avent, Inc.</a>	S-1	333-249076	10.14	September 25, 2020	
10.12#	<a href="#">Management Cash Incentive Plan.</a>	S-1/A	333-249076	10.15	October 9, 2020	
10.13†	<a href="#">Development and License Agreement, dated March 26, 2021, between the Registrant and LianBio Ophthalmology.</a>	10-Q	001-39614	10.1	May 11, 2021	
10.14	<a href="#">Loan and Security Agreement, dated February 2, 2022, by and among Registrant, Hercules Capital, Inc. and Silicon Valley Bank.</a>	10-Q	001-39614	10.1	May 11, 2022	
10.15#	<a href="#">Consulting Agreement, dated August 1, 2020, between the Registrant and Elizabeth Yee-Liu, M.D., as amended.</a>	10-Q	001-39614	10.2	May 11, 2022	
10.16†	<a href="#">Amended and Restated License Agreement, dated June 3, 2022, by and between the Registrant and Flanco Tiergesundheits AG.</a>	10-Q	001-39614	10.1	August 11, 2022	
10.17^	<a href="#">Amended and Restated License Agreement, dated June 3, 2022, by and between the Registrant and Flanco Tiergesundheits AG.</a>	10-Q	001-39614	10.2	August 11, 2022	
10.18	<a href="#">First Amendment to Loan and Security Agreement, dated as of January 5, 2023, by and among Registrant Hercules Capital, Inc. and Silicon Valley Bank.</a>					X
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm.</a>					X
24.1	<a href="#">Power of Attorney (included in the signature page to this Annual Report on Form 10-K).</a>					X

31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	X
31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	X
32.1*	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	X
32.2*	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	X
101.INS	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.	X
101.SCH	XBRL Taxonomy Extension Schema Document.	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	X

- ^ Pursuant to Item 601(a)(5) of Regulation S-K, certain exhibits and schedules have been omitted. The Registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.
- † Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks as the identified confidential portions (i) are not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.
- # Indicates a management contract or compensatory plan.
- \* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the SEC and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

(c) *Financial Statement Schedules.* All schedules have been omitted because the information required to be presented in them is not applicable or is shown in the financial statements or related notes.

**Item 16. Form 10-K Summary**

None.



#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Irvine, State of California, on March 17, 2023.

**Tarsus Pharmaceuticals, Inc.**

/s/ Bobak Azamian, M.D., Ph.D.

Bobak Azamian, M.D., Ph.D.

President, Chief Executive Officer and Board Chairman

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bobak Azamian, M.D., Ph.D., Leonard Greenstein, and Bryan Wahl, M.D., and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Bobak Azamian, M.D., Ph.D. Bobak Azamian, M.D., Ph.D.	President, Chief Executive Officer, and Board Chairman <i>(Principal Executive Officer)</i>	March 17, 2023
/s/ Leonard M. Greenstein Leonard M. Greenstein	Chief Financial Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i>	March 17, 2023
/s/ Scott Morrison Scott Morrison	Director	March 17, 2023
/s/ Bhaskar Chaudhuri, Ph.D. Bhaskar Chaudhuri, Ph.D.	Director	March 17, 2023
/s/ Rosemary Crane Rosemary Crane	Director	March 17, 2023
/s/ Andrew Goldberg, M.D. Andrew Goldberg, M.D.	Director	March 17, 2023
/s/ William J. Link, Ph.D. William J. Link, Ph.D.	Director	March 17, 2023
/s/ Wendy Yarno Wendy Yarno	Director	March 17, 2023
/s/ Elizabeth Yeu-Lin, M.D. Elizabeth Yeu-Lin, M.D.	Director	March 17, 2023



