

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

**FORM S-1
REGISTRATION STATEMENT**

*Under
The Securities Act of 1933*

TARSUS PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

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

15440 Laguna Canyon Road
Irvine, California 92618
(949) 409-9820

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Bobak Azamian, M.D., Ph.D.
President and Chief Executive Officer
Tarsus Pharmaceuticals, Inc.
15440 Laguna Canyon Road
Irvine, California 92618
(949) 409-9820

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Ilan Lovinsky
Jeffrey R. Vetter
Ryan J. Gunderson
Gunderson Dettmer Stough Villeneuve
Franklin & Hachigian, LLP
3570 Carmel Mountain Road, Suite 200
San Diego, California 92130
(858) 436-8000

Leo M. Greenstein
Chief Financial Officer
Tarsus Pharmaceuticals, Inc.
15440 Laguna Canyon Road
Irvine, California 92618
(949) 409-9820

Iliir Mujalovic
Shearman & Sterling LLP
599 Lexington Avenue
New York, New York 10022
(212) 848-4000

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

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)(2)	Amount of Registration Fee (3)
Common Stock, \$0.0001 par value per share	\$	\$

(1) Estimated pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes the aggregate offering price of additional shares that the underwriters have the option to purchase.

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

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

EXPLANATORY NOTE

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting our unaudited financial statements as of and for the three months ended March 31, 2020 and March 31, 2019. While this financial information is otherwise required by Regulation S-X, we reasonably believe that it will not be required to be included in the prospectus at the time of the contemplated offering. We intend to amend this registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion
Preliminary Prospectus dated August 7, 2020

PROSPECTUS

Shares



Tarsus Pharmaceuticals, Inc.

Common Stock

This is Tarsus Pharmaceuticals, Inc.'s initial public offering. We are selling _____ shares of our common stock.

We expect the public offering price to be between \$ _____ and \$ _____ per share. Currently, no public market exists for the shares of our common stock. We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "TARS."

We are an emerging growth company as defined under the U.S. federal securities laws and, as such, may elect to comply with certain reduced public company reporting requirements for this and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in the common stock involves risks that are described in the "[Risk Factors](#)" section beginning on page 15 of this prospectus.

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$ _____	\$ _____
Underwriting discount (1)	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

(1) We refer you to "Underwriting" beginning on page 185 of this prospectus for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional _____ shares of common stock from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares of common stock will be ready for delivery on or about _____, 2020.

BofA Securities

Jefferies

Raymond James

LifeSci Capital

Ladenburg Thalmann

The date of this prospectus is _____, 2020.

TABLE OF CONTENTS

PROSPECTUS SUMMARY	1
RISK FACTORS	15
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	83
MARKET, INDUSTRY AND OTHER DATA	85
USE OF PROCEEDS	86
DIVIDEND POLICY	87
CAPITALIZATION	88
DILUTION	90
SELECTED FINANCIAL DATA	93
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	95
BUSINESS	108
MANAGEMENT	152
EXECUTIVE COMPENSATION	160
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	168
PRINCIPAL STOCKHOLDERS	171
DESCRIPTION OF CAPITAL STOCK	173
SHARES ELIGIBLE FOR FUTURE SALE	178
MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS OF OUR COMMON STOCK	181
UNDERWRITING	185
LEGAL MATTERS	193
EXPERTS	193
WHERE YOU CAN FIND ADDITIONAL INFORMATION	193
INDEX TO FINANCIAL STATEMENTS	F-1

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

PROSPECTUS SUMMARY

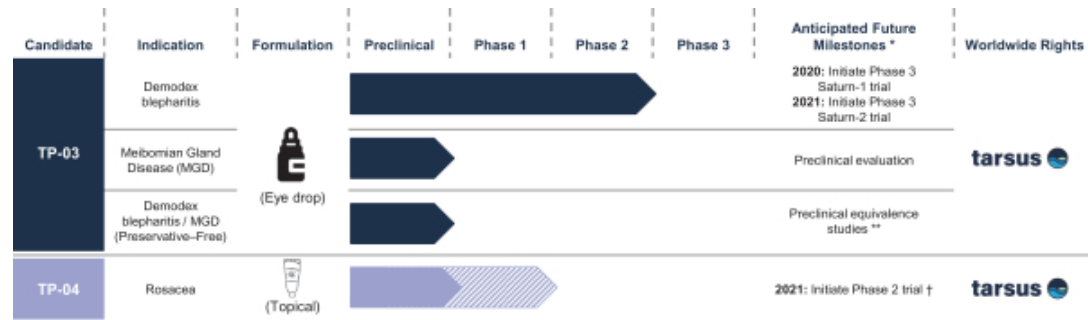
This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all of the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the sections titled “Risk Factors,” “Business,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus before making an investment decision. In this prospectus, unless context requires otherwise, references to “we,” “us,” “our,” “Tarsus,” or “the Company” refer to Tarsus Pharmaceuticals, Inc.

Overview

We are a late clinical-stage biopharmaceutical company focused on the development and commercialization of first-in-class therapeutic candidates to address large market opportunities initially in ophthalmic conditions where there are limited treatment alternatives. Our lead product candidate, TP-03, is a Phase 3 ready, first-in-class, novel therapeutic being developed for the treatment of 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 a condition characterized by inflammation of the eyelid margin, redness and ocular irritation, including a specific type of eyelash dandruff called collarettes in Demodex blepharitis. The healthy interaction of the eyelid and the surface of the eyeball is crucial to ocular health. Poorly controlled and progressive blepharitis can lead to worsening of corneal damage over time and, in extreme cases, blindness. According to published studies, there are an estimated 20 million patients in the United States who suffer from blepharitis, with approximately 45%, or approximately 9 million, of cases caused by Demodex infestation. Further, our internal studies indicate the possibility that the number of Demodex blepharitis cases may be as high as approximately 25 million based on observation of collarettes in patients presenting to eye care clinics. To date, we have completed four Phase 2 trials for TP-03 in Demodex blepharitis, all of which showed highly statistically significant cure and eradication rates and that TP-03 was well tolerated. We intend to commence our first Phase 3 trial, Saturn-1, in 2020 and a second Phase 3 trial, Saturn-2, in 2021 with primary and secondary endpoints consistent with those of the Phase 2 trials. If successful, we expect these trials to support the submission of a new drug application, or NDA, to the Food and Drug Administration, or the FDA, for TP-03 for the treatment of Demodex blepharitis. Furthermore, we intend to pursue marketing authorizations in jurisdictions outside the United States, including Europe and Japan. We believe that, if approved, TP-03 has the potential to be the first FDA-approved therapeutic and become the standard of care for the treatment of Demodex blepharitis.

Our current therapeutic strategy is focused on the clinical development of, for the first time in human medicine, the novel drug, lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific g-aminobutyric acid-gated chloride channels, or GABA-Cl channels. We are advancing our pipeline to address a number of diseases across therapeutic categories including eye care and dermatology. These diseases include Demodex blepharitis, Meibomian Gland Disease, or MGD, and rosacea.

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



* Anticipated milestones are subject to the impact of the ongoing COVID-19 pandemic on our business.
 ** We intend to initiate preclinical equivalence studies with our preservative-free formulation of TP-03 in Demodex blepharitis after NDA submission of the original formulation of TP-03 in Demodex blepharitis.
 † We intend to initiate a Phase 2 trial exploring TP-04 in Rosacea without first conducting Phase 1 trials.

Blepharitis: A Significant, Underserved & Underdiagnosed Market

Blepharitis is a common, chronic ophthalmic condition 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, in extreme cases, blindness. According to published studies, an estimated 20 million patients suffer from blepharitis, and there is growing recognition within the ophthalmic community about Demodex mites as an underlying cause of blepharitis. Demodex mites are the most common ectoparasite found on humans. Demodex mites potentially cause approximately 45% of blepharitis cases, or approximately 9 million patients. Based on our internal studies of collarette prevalence in the eye care office, we believe that the number of Demodex blepharitis patients in the United States may be as high as approximately 25 million. In addition, there is growing awareness among eye care professionals, or ECPs, of a specific type of debris found at the base of the eyelashes, known as collarettes, or cylindrical dandruff, which are highly correlated with Demodex infestation. 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. Demodex blepharitis increases progressively with aging, which is the main risk factor for the condition. These patients commonly present to the offices of ECPs for other ophthalmic conditions besides blepharitis, such as cataract surgery 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 condition in standard practice.

Despite the high prevalence of patients with Demodex blepharitis and growing awareness of the condition amongst ECPs, there are no FDA-approved therapeutics for the treatment of blepharitis or for Demodex blepharitis. Although we believe blepharitis and Demodex blepharitis are significantly underdiagnosed conditions, with limited treatment alternatives, there are already an estimated 2.1 million annual blepharitis diagnoses in the United States. 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 lead to significant irritation and dissatisfaction for patients, and do not eradicate the Demodex mites.

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 indicative of Demodex blepharitis, further validating the accessible opportunity to increase diagnosis

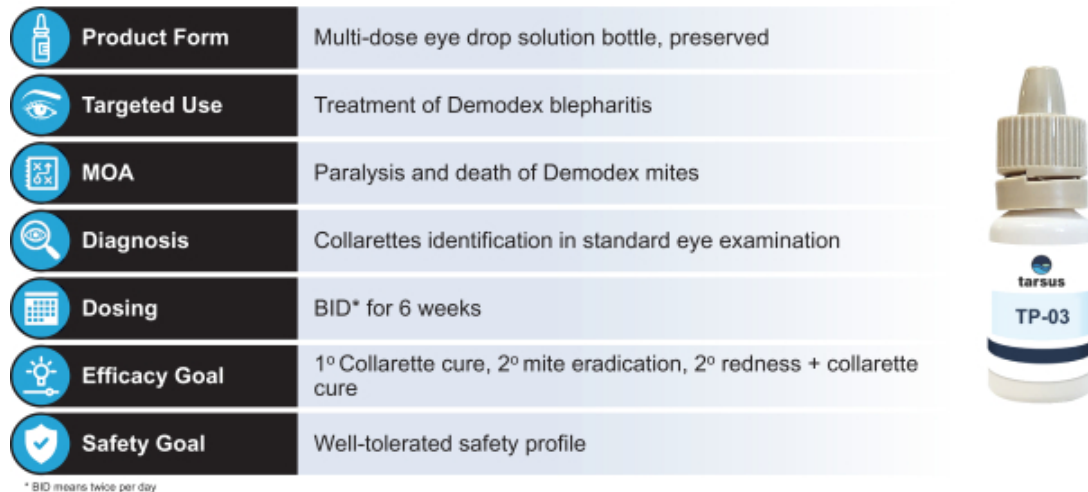
rates amongst patients. In addition, our market research suggests the potential for a high level of adoption of TP-03, if approved. In our surveys, we interviewed 50 ECPs, 96% of whom indicated they would prescribe TP-03 as a first-line treatment for Demodex blepharitis after exposure to the TP-03 target product profile. Since patients continue to have underlying risk of Demodex infestation, there could be a recurrence based on the presence of Demodex mites in the skin even after eradication of Demodex mites from the eyelid as demonstrated in Phase 2 trials with TP-03. Our Phase 2 data from the Mars and Jupiter clinical trials followed patients to one year after treatment and showed meaningful recurrence of Demodex blepharitis within six to nine months, which increased considerably one year after treatment. We believe this data suggests TP-03, if approved, may be used on a chronic, intermittent basis in Demodex blepharitis.

We believe the blepharitis market has the potential to be analogous to other ophthalmic markets that grew significantly once there was a product to address the large, latent demand for an effective therapy. Another ocular surface disease, dry eye, had no approved therapeutic for the condition until 2003. With the approval of Allergan’s Restasis (cyclosporine) in 2003 and concurrent ECP and patient education, the diagnosis rate increased by approximately 12x, growing from 500,000 diagnoses in 2003 to over 6 million diagnoses in 2015. Annual diagnoses rates have been maintained at similar levels since 2015, and in 2016 Restasis generated peak revenue of \$1.5 billion. Blepharitis already has 2.1 million diagnoses per year, despite no approved therapies to help with market awareness, but like dry eye, we believe there is potential for significant market expansion. We believe there is a significant opportunity to increase the diagnosis rate of Demodex blepharitis and build a significant new market with the approval of a safe and effective therapeutic alternative that addresses the underlying cause of the condition.

Our Approach: TP-03

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 first-in-class therapeutic based on the novel drug, lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific GABA-Cl channels.

The following figure provides the characteristics of TP-03 in the Saturn-1 Phase 3 clinical trial:



We have completed four Phase 2 clinical trials to date, along with one additional *ex vivo study*. *Key efficacy endpoints included cure rate based on collarette grade, which we refer to herein as collarette cure rate,*

and mite eradication rate, with TP-03 meeting its primary and secondary endpoints and showing highly statistically significant cure and eradication rates in our two most recent trials, Io and Europa. TP-03 was generally well tolerated throughout these trials.

The results of our Phase 2 trials highlight the robust and consistent clinical efficacy of TP-03 in curing collarettes and eradicating mites which we believe are essential to successfully treat Demodex blepharitis. The Phase 2a Mars trial was a smaller single arm study evaluating the safety and efficacy of TP-03 with a 28-day twice per day, or BID, dosing regimen, with exploratory endpoints including collarette grading score and mite density. We utilized the data from the exploratory endpoints to determine collarette cure rate, defined as 10 or fewer collarettes, and mite eradication rate, defined as zero mites per lash. Both collarette cure and mite eradication rates were assessed at 28 days, which were 86% and 57% respectively. The Phase 2b Jupiter trial was a larger randomized, controlled double-blind trial with collarette grade and mite density as primary and secondary endpoints, respectively. Similarly to the Mars trial, we utilized the collarette grading and mite density data to determine collarette cure and mite eradication rates, which were both defined consistently with those used in the Mars trial. The efficacy observed in the Jupiter trial appeared consistent with the Mars trial, with a collarette cure rate of 88%, and mite eradication rate of 66%, which were statistically significant compared to the vehicle control. We subsequently conducted the Io Phase 2a and Europa Phase 2b trials to evaluate the safety and efficacy of TP-03 formulation for the treatment of Demodex blepharitis. The design of the Io trial took into account feedback from the FDA, and accordingly we defined collarette cure rate to a more stringent definition of two or fewer collarettes on the eyelid and mite eradication rates, with a treatment duration of 42 days. In the Io trial, we utilized for the first time in clinical trials the formulation of TP-03 that is expected to support our NDA submission for Demodex blepharitis. The key differences between the Io and Europa trials, were that Io was a smaller single-arm study, while Europa was slightly larger randomized placebo-controlled study. The observed efficacy in Io and Europa were consistent across both trials, with a collarette cure rate of 72% and 79% respectively, and a mite eradication rate of 78% and 71% respectively. The meaningful and consistent clinical efficacy and safety results we observed across our comprehensive Phase 2 program, provided us with the basis to design and initiate our pivotal Phase 3 program.

The following figure provides a summary of our completed and planned clinical investigations evaluating TP-03 for Demodex blepharitis:

Trial / Study	Design	Objectives	Results	Status	
PoC: Mercury	Ex-vivo mite testing on 80 mites	Ex-vivo mite death count	100% mites dead within 24 hours (p < 0.001)		
Clinical Trials			Collarette Cure Rate***	Mite Eradication Rate	
P2a: Mars *	28-day BID dosing, single arm (n=15) Pilot formulation	Collarette grade Mite density Safety	86% at 28 days (p < 0.05)	57% at 28 days (p < 0.05)	
P2b: Jupiter *	28-day BID dosing, randomized 1:1 (n=60) Pilot formulation	1 ^o – Collarette grade 2 ^o – Mite density Safety	88% at 28 days (p < 0.001)	67% at 28 days (p < 0.005)	
P2a: Io	42-day BID dosing, single arm (n=18) Current formulation	1 ^o – Collarette cure 2 ^o – Mite eradication Safety	72% at 42 days (p < 0.05)	78% at 42 days (p < 0.05)	
P2b: Europa	42-day BID dosing, randomized 1:1 (n=54) Current formulation	1 ^o – Collarette cure 2 ^o – Mite eradication 2 ^o – Redness Composite Safety	80% at 42 days (p < 0.001)	73% at 42 days (p = 0.003)	
P3: Saturn-1	42-day BID dosing, randomized 1:1 (n=350) Current formulation **	1 ^o – Collarette cure 2 ^o – Mite eradication 2 ^o – Redness Composite Safety	Initiate trial in 2020		
P3: Saturn-2	42-day BID dosing, randomized 1:1 (n=350) Current formulation **	1 ^o – Collarette cure 2 ^o – Mite eradication 2 ^o – Redness Composite Safety	Initiate trial in 2021		

* The Mars and Jupiter trials used collarette grade as an endpoint, which has been translated into a collarette cure (defined as <10 collarettes). This is different from the collarette cure (defined as ≤2 collarettes) endpoint used in Io, Europa and the planned Saturn-1/2 trials. Mite density is translated into mite eradication, which is defined as 0 mites consistently throughout trials.

** Expected design pending FDA feedback.

*** Primary endpoint in Io, Europa, and intended in Saturn-1 and Saturn-2, is cure based on collarette grade.

Represents pivotal trial Same endpoints and formulation of TP-03 as Saturn trials

We plan to evaluate TP-03 in two Phase 3 pivotal registration trial, referred to as Saturn-1 and Saturn-2. Saturn-1 is a Phase 3, randomized, controlled, double-blind trial to evaluate the safety and efficacy of TP-03 in approximately 350 Demodex blepharitis patients in multiple centers in the United States. Enrollment of Saturn-1 is expected to begin in 2020 and top-line data is expected in 2021, subject to the impact of the ongoing COVID-19 pandemic. Saturn-2, our confirmatory Phase 3 randomized, controlled, double-blind trial, has a highly comparable design to that of Saturn-1 and is also expected to enroll approximately 350 Demodex blepharitis patients. Enrollment of Saturn-2 is expected to begin in 2021, subject to the impact of the ongoing COVID-19 pandemic. We expect these trials to support the potential submission of an NDA for TP-03 for the treatment of Demodex blepharitis.

We also intend to explore the therapeutic potential of TP-03 for a second ophthalmic condition, MGD, commonly characterized in part by a widespread clogging of the meibomian glands that 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 United States, MGD prevalence has been found to be approximately two-thirds of that 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*. While dry eye is a multi-factorial disease, TP-03 is designed to relieve some of the key elements of MGD by virtue of causing the death of the *Demodex brevis* mites.

Beyond TP-03, we are developing TP-04 for the potential treatment of rosacea, 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 United States are affected by rosacea and a study we conducted estimates rosacea prevalence can represent up to 5.4% of the global population.

Our Team

We have assembled a team with extensive experience developing and commercializing leading ophthalmic products and therapies. Members of our management team and board of directors have founded and led several biopharmaceutical companies including those in the ophthalmic care space, such as Oyster Point Pharma and Oculeve, and have been pivotal in the development and commercialization of various leading ophthalmic products, including the dry eye therapy, Restasis. We intend to leverage this expertise and experience to rapidly pursue the development of TP-03 and any other future product candidates that we may identify and develop. We are supported by healthcare dedicated financial investors, which include Aperture Venture Partners, Flying L Ventures, Horowitz Limited Partnership, Frazier Life Sciences, Visionary Ventures and Vivo Capital.

Our Strengths and Differentiation

We believe our company and our product candidates have the following key distinguishing characteristics:

- **Compelling efficacy and safety data.** We have observed TP-03's compelling efficacy and safety in our four Phase 2 clinical trials – Mars, Jupiter, Io and Europa – in which treatment with TP-03 resulted in highly statistically significant levels of collarette cure rate and mite eradication rate, and was well tolerated. Our Phase 3 trials, Saturn-1 and Saturn-2, are expected to utilize trial designs that are highly comparable to those of the Phase 2 Io and Europa trials.
- **Large, underserved and underdiagnosed blepharitis market with a significant opportunity for growth.** Although we believe blepharitis and Demodex blepharitis are significantly underdiagnosed conditions, with limited treatment alternatives, there are already an estimated 2.1 million annual blepharitis diagnoses in the United States. However, we believe the market opportunity may be substantially larger. According to published studies, there are an estimated 20 million patients in the United States that suffer from blepharitis with approximately 45%, or approximately 9 million, of cases caused by Demodex infestation. Further, our internal studies indicate the possibility that the number of Demodex blepharitis cases may be as high as approximately 25 million based on observation of collarettes in patients presenting to eye care clinics. We believe the blepharitis market is analogous to other ophthalmic markets, such as dry eye, where diagnoses grew significantly once there was a product to address the large, latent demand for an effective therapy, as was observed with the approval of Allergan's Restasis in 2003.
- **Novel chemistry developed for the first time in human medicine.** Our current therapeutic strategy is focused on the clinical development of, for the first time in human medicine, the novel drug, lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific GABA-Cl channels. Our pipeline aims to address a number of diseases across therapeutic categories including eye care and dermatology.
- **Additional opportunities beyond Demodex blepharitis.** Like blepharitis, MGD may also be caused by Demodex infestation, and we intend to explore the therapeutic potential for TP-03 in this indication. In the United States, MGD prevalence has been found to be approximately two-thirds of that of the estimated 34 million dry eye patient population. Further, we are developing TP-04 for the potential treatment of rosacea, a condition that affects approximately 16 million patients per year in the United States.

- **Experienced management team and board of directors supported by high quality investor base.** We have built a leadership team with significant experience in developing and commercializing therapeutic products for ophthalmic conditions. Our management team and board of directors have founded and led several companies in the ophthalmic care space, including Oyster Point Pharma and Oculeve, and have been pivotal in the development and commercialization of various leading ophthalmic products, including the dry eye therapy, Restasis.

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 through clinical development and eventual approval for the treatment of Demodex blepharitis.** We have observed in multiple Phase 2 trials across 147 patients that TP-03 results in collarette cure and mite eradication, the same clinical endpoints that will be utilized in our pivotal Phase 3 trials. We expect enrollment of our first pivotal trial, Saturn-1, to begin in 2020 and top-line data is anticipated in 2021, subject to the impact of the ongoing COVID-19 pandemic. Enrollment of our second pivotal trial, Saturn-2, is expected to begin in 2021, subject to the impact of the ongoing COVID-19 pandemic.
- **Educate ECPs and establish our own specialty sales organization to commercialize TP-03 in the United States.** 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 25,000 prescribing ECPs in the United States. Throughout our commercialization efforts, we intend to educate ECPs on of Demodex blepharitis and how to diagnose it with a standard eye examination.
- **Expand the label of TP-03 for other indications and develop our pipeline to bring a novel, first-in-class, anti-parasitic molecule to unmet needs across human medicine, including MGD and rosacea.** Like blepharitis, MGD may also be caused by Demodex infestation, and we intend to explore the therapeutic potential for TP-03 in the indication. Further, we plan to expand our pipeline of novel, differentiated products that target parasites to treat diseases with large market opportunities, like rosacea.
- **Evaluate and selectively enter into strategic partnerships to maximize the potential of our pipeline and the scope of our eye care product offerings.** We have retained our rights globally to all of our indications for use in humans. Given the potential to treat patients worldwide we may opportunistically enter into strategic partnerships around certain product candidates, disease or geographic regions.

Risks Related to Our Business

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section entitled “Risk Factors” immediately following this prospectus summary. These risks include, among others:

- We are a late clinical-stage 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.

- Even if this offering is successful, we will need to obtain substantial 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.
- The COVID-19 pandemic, which began in late 2019 and has spread worldwide, may 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.
- 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 or 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 payors and others in the medical community, and the market opportunity for these products may be smaller than we estimate.
- We will need to develop and expand our company in terms of operations and employees, which we expect to include 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.
- 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 certain of our products, including our lead product candidate, TP-03 for the potential treatment of Demodex blepharitis and MGD, and TP-04 for the potential treatment of rosacea, is dependent on intellectual property we license from Elanco Tiergesundheit AG, or Elanco.
- 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.

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, Irvine, California 92618. Our telephone number is (949) 409-9820. Our website address is www.tarsusrx.com. Information contained on the website is not incorporated by reference into this prospectus.

We have included our website address in this prospectus solely as an inactive textual reference.

Tarsus Therapeutics, Tarsus, and Tarsus Pharmaceuticals, Inc., our logo and other registered or common law trade names, trademarks or service marks of Tarsus appearing in this prospectus are the property of Tarsus. This prospectus 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 prospectus 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.

Implications of Being an Emerging Growth Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual gross revenue; (ii) the date we qualify as a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, with at least \$700 million of equity securities held by non-affiliates; (iii) the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; or (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering. As a result of this status, we have taken advantage of certain exemptions from various reporting requirements in this prospectus that are applicable to other publicly-traded entities that are not emerging growth companies and may elect to take advantage of other exemptions from reporting requirements in our future filings with the SEC. In particular, in this prospectus, these exemptions include:

- the option to present only two years of audited financial statements and only two years of Management's Discussion and Analysis of Financial Condition and Results of Operations;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes Oxley Act;
- 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;" and
- 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.

As a result, we do not know if some investors will find our common stock less attractive. The result may be a less active trading market for our common stock, and the price of our common stock may become more volatile.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, upon completion of this offering, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies that are not emerging growth companies. Even after we no longer qualify as an emerging growth company, we may qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million.

THE OFFERING

Issuer	Tarsus Pharmaceuticals, Inc.
Shares of common stock offered by us	shares
Shares of common stock to be outstanding immediately after this offering	shares (or additional shares in full) shares if the underwriters exercise their option to purchase
Underwriters' option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of our common stock. The underwriters can exercise this option at any time within 30 days after the date of this prospectus.
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$ million, or \$ million if the underwriters exercise their option to purchase additional shares in full, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming an initial public offering price of \$ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus.</p> <p>We intend to use the net proceeds from this offering to complete the development of TP-03 for the treatment Demodex blepharitis and the remaining proceeds to fund the development of our product pipeline, as well as for other general corporate purposes. See "Use of Proceeds" on page 86 for additional information.</p>
Risk Factors	See "Risk Factors" beginning on page 15 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Proposed Nasdaq Global Market trading symbol	"TARS"

The number of shares of our common stock to be outstanding after this offering is based on shares of our common stock outstanding as of June 30, 2020 and excludes the following:

- shares of common stock issuable upon the exercise of options outstanding as of June 30, 2020, with a weighted-average exercise price of \$ per share;
- shares of common stock issuable upon the exercise of options granted after June 30, 2020, at a weighted-average exercise price of \$ per share;
- shares of common stock, legally issued upon the early exercise of certain stock options, but are subject to service conditions and the right of repurchase, that were outstanding as of June 30, 2020;

- shares of restricted common stock granted to our founders that are subject to service conditions and the right of repurchase, that were outstanding as of June 30, 2020;
- shares of common stock reserved for future issuance under our 2016 Stock Plan, as amended, or the 2016 Plan, as of June 30, 2020, which shares will be added to the shares to be reserved under our 2020 Equity Incentive Plan, or the 2020 Plan, upon its effectiveness; and
- shares of common stock reserved for future issuance under our 2020 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- shares of common stock reserved for issuance under our 2020 Employee Stock Purchase Plan, or the 2020 ESPP, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

Unless otherwise indicated, all information in this prospectus assumes:

- a -for- reverse stock split of our common stock to be effective on , 2020;
- the conversion of all outstanding shares of our preferred stock into an aggregate of shares of common stock immediately prior to and in connection with the completion of this offering;
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the completion of this offering;
- no exercise of the underwriters' option to purchase additional shares; and
- no exercise of the outstanding options described above after June 30, 2020.

SUMMARY FINANCIAL DATA

The summary statements of operations data for the years ended December 31, 2018 and 2019 are derived from our audited financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of results that may be expected in the future. You should read these summary financial data together with our financial statements and related notes appearing elsewhere in this prospectus and the information in the sections titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The selected financial data in this section are not intended to replace our financial statements and the related notes and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

	Years Ended December 31,	
	2018	2019
	(in thousands, except share and per share data)	
Statement of Operations Data:		
Operating expenses:		
Research and development	\$ 901	\$ 3,162
General and administrative	449	1,136
Total operating expenses	<u>1,350</u>	<u>4,298</u>
Loss from operations before other income (expense) and income taxes	<u>(1,350)</u>	<u>(4,298)</u>
Other income (expense):		
Interest income (expense), net	32	(40)
Loss on extinguishment of related party convertible notes	—	(255)
Change in fair value of derivative liabilities	—	(76)
Total other income (expense)	<u>32</u>	<u>(371)</u>
Provision for income taxes	<u>(1)</u>	<u>(1)</u>
Net loss and comprehensive loss	<u>\$ (1,319)</u>	<u>\$ (4,670)</u>
Net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	<u>\$ (0.10)</u>	<u>\$ (0.26)</u>
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	<u>13,068,854</u>	<u>17,728,991</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽¹⁾		<u>\$ (0.15)</u>
Weighted-average shares outstanding used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽¹⁾		<u>32,008,512</u>

(1) For the calculation of our basic and diluted net loss per share attributable to common stockholders, unaudited basic and diluted pro forma net loss per share and weighted-average number of shares used in the computation of the per share amounts, see Note 6 and Note 7 to our financial statements included elsewhere in this prospectus.

[Table of Contents](#)

	As of June 30, 2020 (unaudited)		
	Actual	Pro Forma (1)	Pro Forma As Adjusted (2)
	(in thousands)		
Balance Sheet Data			
Cash and cash equivalents			
Working capital (3)			
Total assets			
Preferred stock			
Total stockholders' (deficit) equity			

(1) The pro forma balance sheet data gives effect to the automatic conversion of all outstanding shares of our Preferred Stock as of _____, 2020 into an aggregate of _____ shares of common stock, which will occur immediately prior to the completion of this offering and the filing and effectiveness of our amended and restated certificate of incorporation, which will occur in connection with the closing of this offering.

(2) Reflects the pro forma adjustments described in footnote (1) above and the issuance and sale of shares of common stock in this offering at the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our audited financial statements and related notes appearing at the end of this prospectus for further details regarding our current assets and current liabilities.

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 prospectus, including our financial statements and the related notes appearing at the end of this prospectus. 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. This prospectus 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 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 and have incurred net losses in each reporting period since our company’s formation in 2016. We have funded our operations primarily from the sale and issuance of redeemable convertible preferred stock and convertible promissory notes. For the years ended December 31, 2019 and 2018, our net losses were \$4.7 million and \$1.3 million, respectively. As of December 31, 2019, we had an accumulated deficit of \$6.0 million. 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 a few years, 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:

- 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;
- 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;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify, assess, acquire or develop additional product candidates;
- acquire or in-license other product candidates and technologies;

Table of Contents

- 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:

- we are required by regulatory authorities to perform trials or studies in addition to, or different than, those that we currently expect;
- there are any delays in establishing appropriate manufacturing arrangements for or completing the development of any of our product candidates; 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. 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 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

Table of Contents

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, and 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 conduct additional clinical development, seek and obtain regulatory approval, secure adequate manufacturing supply to support commercial sales and build a commercial organization. We have not yet demonstrated our ability to complete pivotal clinical trials. 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 payors, 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 this offering is successful, we will need to obtain substantial 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 and convertible promissory notes. 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, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company.

As of December 31, 2019, we had \$58.0 million in cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our anticipated level of operations through at least the next 12 months without the proceeds from this offering. With the expected net proceeds from this offering, we believe that our cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through the end of 2021. Accordingly, the expected net proceeds from this offering will not be sufficient for us to fund any of our product candidates through regulatory approval and commercialization, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We may also need to raise additional funds sooner if we choose to pursue additional indications for our product candidates or otherwise expand more rapidly than we presently anticipate.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of 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, 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;

Table of Contents

- the scope and costs of manufacturing development and commercial manufacturing activities and our ability to scale them up;
- 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 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 do not expect to have any products commercially available for sale for many years, if at all. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. 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. For example, market volatility resulting from the COVID-19 pandemic or any other future infectious diseases, epidemics or pandemics could also adversely impact our ability to access capital as and when needed. 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.

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 revenue unless and until either TP-03 or another product candidate receives the regulatory approvals necessary for

[Table of Contents](#)

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:

- successful and timely completion of preclinical and clinical development of our product candidates, including the clinical development of TP-03 for the treatment of Demodex blepharitis or other indications and any other future product candidates;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development, both in the United States and internationally, of our product candidates;
- timely receipt of regulatory approvals from applicable regulatory authorities for TP-03 or any other product candidates for which we successfully complete clinical development;
- 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 United States for a particular indication, such as TP-04 for the potential treatment of rosacea;
- successful commercial launch following any regulatory approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety and efficacy profile both prior to and following any marketing approval of our product candidates;
- successfully educating ECPs about Demodex blepharitis and related diagnosis;
- commercial acceptance of TP-03 and any of our other product candidates by patients, the medical community and third-party payors;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States 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 payors for product candidates that we develop;

Table of Contents

- 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.

The COVID-19 pandemic, which began in late 2019 and has spread worldwide, may 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, has 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 have 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. We have implemented a work-from-home 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. 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

[Table of Contents](#)

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 investigational new drug applications, or INDs;
- 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;

Table of Contents

- 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 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.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, 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 a combination 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. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or liens, making acquisitions, selling or licensing our assets, redeeming our stock, making certain investments, making capital expenditures or declaring dividends.

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

[Table of Contents](#)

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.

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 soon 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, particularly after the expiration of the lock-up agreements described herein. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

In connection with becoming a public company, we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these

Table of Contents

development activities. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We may not realize the benefits of any acquisitions, in-license or other collaborations or strategic alliances that we enter into.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because we are unable to agree on commercial terms, or because third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of 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 of June 30, 2020, we had 12 full-time employees. As we advance our research and development programs, 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 any of our 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 conduct 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

[Table of Contents](#)

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.

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. 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.

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

Earthquakes or other natural disasters 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

[Table of Contents](#)

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 recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Additionally, the COVID-19 pandemic has caused significant disruptions to the U.S., regional and global economies and has contributed to significant volatility and negative pressure in financial markets. A severe or prolonged economic downturn, or any prolonged economic downturn caused by the COVID-19 pandemic, could result in a variety of risks to our business, including reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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, or the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards, or 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 United States enacted the “Tax Cuts and Jobs Act,” or 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.

[Table of Contents](#)

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or the FFCR Act, was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act, or the 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

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, particularly TP-03 for the treatment of Demodex blepharitis, 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.

We have not yet completed any Phase 3 trials for any product candidate. 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 2 clinical trials for Demodex blepharitis in our Phase 3 trials, Saturn-1 and Saturn-2. 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

Table of Contents

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.

We currently have one product candidate, TP-03, in clinical development and its risk of failure is high. For example, use of TP-03 requires the patient to follow a prescribed technique to administer the eye drops. Failure to properly administer the eye drops by the patient or inappropriate technique demonstration by the eye care practitioners, may adversely affect the outcome of TP-03 in demonstrating efficacy in one or more clinical trials. We are unable to predict if this product candidate or any of our future product candidates that advance into clinical trials will prove safe or effective in humans or will obtain marketing approval. 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 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. 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 TP-03, our other 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;

Table of Contents

- 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 ongoing COVID-19 pandemic, including with respect to the conduct of ongoing clinical trials, receipt of product candidates or other materials, submission of New Drug Applications, or 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

Table of Contents

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.

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, 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 payors 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 payors 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 payors on the benefits of our product candidates may require significant resources and may not be successful.

Further, even if TP-03 demonstrates promising or superior clinical results and 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

Table of Contents

treating symptoms consistent with Demodex blepharitis. A key tenant 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 likelihood that the disease will recur despite mite eradication and the necessity 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 payors 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.

Table of Contents

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.

Most of our operations to date have been limited to preclinical studies and clinical trials. We have completed Phase 2 clinical trials for TP-03 for the treatment of Demodex blepharitis and expect to initiate our first Phase 3 clinical trials for the same indication, Saturn-1, for TP-03 in 2020 and Saturn-2 for TP-03 in 2021 and initiate clinical trials for our other product candidate in the future. As a result, we will need to expand our clinical operations, quality and regulatory capabilities to support these activities.

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.

Our clinical trials to date have been small, and we may not be able to replicate our results from completed trials in Phase 3 trials.

Our clinical trials conducted to date, including for TP-03 for the treatment of Demodex blepharitis, have been small, each with fewer than 60 persons, and have advanced through Phase 1 and Phase 2. For example, the clinical trial which had the highest patient population to date was our Phase 2b Europa clinical trial, which enrolled 54 patients. Our Phase 3 clinical trials will be conducted with larger patient populations, such as Saturn-1 and Saturn-2 to evaluate TP-03 for the treatment of Demodex blepharitis, in which we plan to enroll approximately 350 patients each. In these later trials, additional risks, including previously unidentified low incidence safety risks or lack of efficacy may materialize. Adverse or inconclusive results in these later clinical trials may, despite initially promising results, result in such product candidate not receiving requisite approvals for marketing and sale, and there is a risk that additional clinical trials will be required to obtain such approvals or that our clinical development program will be required to be altered, which would result in increased costs, significant delays to filing with regulatory authorities, filing for a narrower indication than previously anticipated or the abandonment of efforts to commercialization such product candidate.

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;

Table of Contents

- 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 the ongoing COVID-19 pandemic; 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.

The most commonly reported adverse events in TP-03 to date were mild transient ocular burning after administration for less than 10 seconds. One patient in the Europa clinical trial also reported mild burning and blurriness after administration that lasted the entire treatment period. 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 TP-03 or any other product candidate has 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.

[Table of Contents](#)

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 Risk Evaluation and Mitigation Strategy, or 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, or CMC, and our proposed clinical trial protocol, as part of an IND. The initiation of clinical trials in the European Union, or 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;

Table of Contents

- 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 good manufacturing practice, or 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, or 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, or 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 very limited marketing team and no sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical

[Table of Contents](#)

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.

The market for blepharitis and Demodex blepharitis may be not be similar to the market for dry eye.

The markets for blepharitis and Demodex blepharitis may prove to be materially different from the dry eye market that grew significantly once there was an approved product. Even if we obtain approval for TP-03 for the treatment of Demodex blepharitis and commercialize TP-03 in this indication, we may not be able to expand the market for Demodex blepharitis materially or at all or increase awareness of Demodex blepharitis to an extent similar to the dry eye market expansion induced by commercial dry eye product, Restasis, or at all. Our inability to grow the market in a similar way to the dry eye market may occur due to differences in the underlying diseases, different ECP or patient attitudes towards the diseases, symptoms or treatment, changes over time in attitudes towards direct to patient marketing, different reimbursement and coverage, and differences in key assumptions which we have not taken into account in our analysis.

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

TP-03 is a presentation of lotilaner, the API, formulated into an eye drop formulation. TP-04 is likewise a presentation of lotilaner, formulated into topical cream. 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 and TP-04 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 payors, 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

Table of Contents

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 United States. Current treatments for blepharitis in the United States 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.

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

[Table of Contents](#)

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.

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 United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, 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 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. We are evaluating the opportunities for the development and commercialization of our product candidates in 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;

Table of Contents

- 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.

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 all of our completed clinical trials for our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We have conducted all of our clinical trials outside the United States, including our Phase 2 clinical trials 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 United States. Since we have yet to complete any clinical trials in the United States, it is possible that we may not be able to replicate the efficacy and safety results of our completed Phase 2 trials in the United States. 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 support of our potential NDA submission for TP-03 for the treatment of Demodex blepharitis.

Although the FDA may accept data from clinical trials conducted outside the United States, 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 United States. 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 United States, 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.

Table of Contents

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States and if return to conduct trials outside of the United States, 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. If we were required to conduct additional clinical trials, our costs for developing TP-03 for treating MGD would be substantially higher and the timing of any regulatory approval, if any, would be substantially extended, which could adversely affect our results of operations.

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

As product candidates proceed through pre-clinical studies to late-stage clinical trials towards potential 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 processes 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. Such changes may also require additional testing, FDA notification or FDA approval. 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 commence sales and generate revenue. For example, we intend to develop a preservative-free formulation for TP-03, which we expect to be completed after the submission of

Table of Contents

the NDA for Demodex blepharitis and used for commercialization. We intend to initiate preclinical equivalence studies with this preservative-free formulation after the NDA submission of the current formulation of TP-03 for Demodex blepharitis. However, there can be no assurance that the FDA will not require us to conduct studies or trials in addition to these preclinical equivalence studies, which would mean additional costs and potentially delays in our approval of TP-03 for the treatment of Demodex blepharitis.

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

We have entered into a license agreement with Elanco granting us worldwide development and marketing rights (including sublicense rights) to lotilaner for the treatment or cure of any eye or skin condition in humans, or the Elanco Agreement, and may in the future enter into in-license agreements with multiple licensors and strategic agreements, which, subject us 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 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 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 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.

Table of Contents

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 and TP-04 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

Table of Contents

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 the ongoing 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.

Table of Contents

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. 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.

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. In addition, the COVID-19 pandemic may impact our ability to procure sufficient supplies for the development of our product candidates. The extent of this impact will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

Table of Contents

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 licensing agreement 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.

If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to sell, market and distribute our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties, or use a hybrid model incorporating both of these approaches.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- our inability to equip sales personnel with effective materials, including medical and sales literature to help them educate ECPs regarding the indications we are targeting and our products, if approved;
- the inability of sales personnel to obtain access to ECPs or persuade adequate numbers of ECPs to prescribe any future medicines;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue to us are likely to be lower than if we were to market and sell any medicines that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market our medicines effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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 certain of our products, including our lead product candidate, TP-03 for the potential treatment of Demodex blepharitis and MGD, and TP-04 for the potential treatment of rosacea, is dependent on intellectual property we license from Elanco. If we breach our agreement with Elanco or the agreement is terminated, we could lose license rights that are important to our business.

Pursuant to the Elanco Agreement, we acquired an exclusive, worldwide, sublicensable license to certain intellectual property of Elanco for the development, marketing and commercialization of lotilaner for the treatment, prevention, palliation or cure of any eye or skin disease or condition in humans. The Elanco Agreement imposes various development, regulatory, commercial diligence, financial and other obligations on us. If we fail to comply with our obligations under the Elanco Agreement, or otherwise materially breach the Elanco Agreement, and fail to remedy such failure or cure such breach within 60 days, Elanco will have the right to terminate the Elanco Agreement. If we fail to meet any milestones by the achievement deadlines set forth in the 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 Elanco Agreement. If we fail to meet certain dermatological milestones by the achievement deadlines set forth in the 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 Elanco Agreement to the treatment, palliation, prevention or cure of eye diseases or conditions in humans only. If the Elanco Agreement is terminated or our field of use is reduced to eye and skin conditions only by Elanco, we would lose our 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 and TP-04 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 or TP-04 is covered by the affected patents. Accordingly, the loss of our license or the termination of our license for skin diseases and conditions 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 United States 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 United States 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 which protect our product candidates or their intended uses or which 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

[Table of Contents](#)

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 United States is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States 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 freedom to operate analysis for patents 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 or TP-04, we may not successfully find patents that our products or product candidates, including TP-03 or TP-04, may infringe. If we are unable to secure and maintain freedom to operate, 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 United States 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 United States 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 United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize 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

Table of Contents

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 United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and 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 United States 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 United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of 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 U.S. Patent and Trademark Office, or 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

Table of Contents

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 United States 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 freedom to operate analysis for patents 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 secure and maintain freedom to operate, 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 United States 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. We have entered into a license agreement with Elanco granting us worldwide development and marketing rights (including sublicense rights) to lotilaner for the treatment or cure of any eye or skin disease or condition in humans. We plan to utilize these license rights in developing and marketing our TP-03 and TP-04 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;

Table of Contents

- 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 enter into 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;

Table of Contents

- 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 prospectus also apply to the activities of our collaborators.

[Table of Contents](#)

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 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 the 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

[Table of Contents](#)

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 on 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.

We have pending U.S. and foreign patent applications in our portfolio, however, 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 covered by our patents and patent applications;

Table of Contents

- 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 United States 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 United States 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

Table of Contents

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 United States, 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 United States, 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-United States 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 United States 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.

Table of Contents

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, 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. 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.

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

[Table of Contents](#)

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 United States, 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 relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States 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 United States 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 United States could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the 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 United States 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 United States 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 which 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 United States. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States 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

Table of Contents

from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States 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 United States 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.

[Table of Contents](#)

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;

Table of Contents

- the Supreme Court of the United States, 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 United States, 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 United States. 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,

Table of Contents

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.

Table of Contents

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 United States 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 payors both federally and on the state level in the United States 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 United States, 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; (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 Centers for Medicare & Medicaid Services, or 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 repeal or replace, and the Trump administration to alter the implementation of, certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017, or the TCJA, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a federal district court in Texas ruled the individual mandate in the absence of the tax penalty is unconstitutional and, because it is a critical and inseparable feature of the Affordable Care Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the District Court's ruling but remanded the case back to the District Court as to the question of severability. On March 2, 2020, the United States Supreme Court granted certiorari to review this case, which is expected to be decided by mid-2021. Additionally, the Further Consolidated Appropriations Act of 2020, Pub. L. No. 116-94 permanently eliminated, effective January 1, 2020, the Affordable Care Act -mandated "Cadillac" tax on high-cost employer-sponsored health coverage and the medical device excise tax on non-exempt medical devices and, effective January 1, 2021, also eliminates the annual fee imposed on certain health insurance providers based on market share. 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 and to close the coverage gap in most

Table of Contents

Medicare drug plans, commonly referred to as the “donut hole.” In the future, Congress may consider other legislation to repeal or replace elements of the Affordable Care Act, agencies may further alter their implementation of elements of the Affordable Care Act, and other judicial challenges to elements of the Affordable Care Act may be brought. The extent to which any such changes may impact our business or financial condition is uncertain.

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 and will remain in effect through 2020 unless additional Congressional action is taken, with the exception of a temporary suspension of the 2% cut in Medicare payments from May 1, 2020, through December 31, 2020, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, signed into law in March 2020 and designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic. The American Taxpayer Relief Act of 2012, or ATRA, among other things, reduced Medicare payments to several 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, or MACRA, which first affected physician payment in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement.

Also, 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. For example, at the federal level, the Trump administration’s budget for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. On July 24, 2020, President Trump signed several executive orders directed toward lowering drug prices. Individual states in the United States 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 payors. 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 United States 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.

Table of Contents

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, 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 United States 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 intend to adopt a code of conduct applicable to all of our employees prior to completion of this offering, 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

Table of Contents

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.

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 payors 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 payors 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 include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other the other hand. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor, or for which no exception or safe harbor is available, may be subject to scrutiny;

Table of Contents

- federal civil laws, such as the False Claims Act, or the FCA, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds, and knowingly making, using or causing to be made or used a false record or 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. Actions under the FCA may be brought by the U.S. Attorney General or as a qui tam action by a private individual (a whistleblower) in the name of the government and the individual, and the whistleblower may share in any monetary recovery. Many pharmaceutical companies have been investigated and have reached substantial settlements under the federal civil FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product. In addition, 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 FCA. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false or fraudulent claim or statement for violations. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Settlements may require companies to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, among other things, imposes criminal liability for knowingly or willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;

Table of Contents

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the federal Physician Payments Sunshine Act, implemented as the Open Payments Program, requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback laws, false claims laws, transparency laws and misleading advertising laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers, and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

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 United States Congress continues to strengthen the arsenal of enforcement tools. The BBA of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. 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

Table of Contents

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 payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and

[Table of Contents](#)

cost effectiveness data for the use of our products to the payor. 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 payors, 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 United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors 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 payor may depend upon a number of factors, including the third-party payor'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 payors 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 payor, 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 payors 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

[Table of Contents](#)

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 United States, 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 United States, 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 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 as amended by HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose 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 California Consumer Privacy Act, or the CCPA, which came into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used, by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also provides a private right of action (with the potential for class actions) for certain data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

International data protection laws, including the EU General Data Protection Regulation, or GDPR, may also apply to health-related and other personal information obtained outside of the United States. The GDPR extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines 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 put in place additional mechanisms to ensure compliance with the GDPR. This may be onerous and if our

[Table of Contents](#)

efforts to comply with the GDPR or other applicable EU laws and regulations are not successful, it could adversely affect our business. The GDPR prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, 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. In particular, on July 16, 2020, the Court of Justice of the European Union, in the case of *Data Protection Commissioner v. Facebook Ireland Limited, Maximillian Schrems* (Case C-311/18), or *Schrems II*, invalidated the EU-U.S. Privacy Shield Program for transfers of personal data from the EU to the United States, and added further uncertainty and complexity to the use of the Standard Contractual Clauses as a compliance mechanism for transfers of personal data outside the EU.

In addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfers from the EEA to the United Kingdom will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU. During the period of "transition" (i.e., until December 31, 2020), EU law will continue to apply in the UK, including the GDPR, after which the GDPR will be converted into UK law. Beginning in 2021, the UK will be a "third country" under the GDPR. We may incur liabilities, expenses, costs, and other operational losses under GDPR and applicable EU Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

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. Participation is required for federal funds to be available for our covered outpatient drugs under Medicaid and, if applicable, Medicare Part B. Under the Medicaid Drug Rebate Program, we would be

[Table of Contents](#)

required to pay a 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 B. 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, or VA, Federal Supply Schedule, or 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, U.S. Department of Veterans Affairs, U.S. Department of Defense, or the DoD, Public Health Service and U.S. Coast Guard, that is no higher than the statutory Federal Ceiling Price. 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.

Risks Related to our Common Stock and to this Offering

There has been no prior public market for our common stock, the stock price of our common stock may be volatile or may decline regardless of our operating performance and you may not be able to resell your shares at or above the initial public offering price.

There has been no public market for our common stock prior to this offering. The initial public offering price for our common stock will be determined through negotiations between the underwriters and us and may vary from the market price of our common stock following this offering. If you purchase shares of our common stock in this offering, you may not be able to resell those shares at or above the initial public offering price. An active or liquid market in our common stock may not develop upon the completion of this offering or, if it does develop, it may not be sustainable. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- 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;

Table of Contents

- 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 United States and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development or commercialization goals or regulatory approval milestones in the timeframe we announce;
- 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 prospectus.

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. Securities and industry analysts do not currently, and may

Table of Contents

never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if 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.

If you purchase shares of our common stock in this offering, you will experience substantial and immediate dilution.

If you purchase shares of our common stock in this offering, you will experience substantial and immediate dilution in the pro forma net tangible book value per share of \$ _____ per share as of June 30, 2020, based on an assumed initial public offering price of our common stock of \$ _____ per share, the midpoint of the price range on the cover page of this prospectus, because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock. You will experience additional dilution upon exercise of options to purchase common stock under our equity incentive plans, upon vesting of options to purchase common stock under our equity incentive plans, if we issue restricted stock to our employees under our equity incentive plans or if we otherwise issue additional shares of our common stock.

Substantial amounts of our outstanding shares may be sold into the market when lock-up periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. After this offering, we will have _____ outstanding shares of our common stock, based on the number of shares outstanding as of June 30, 2020. All of the shares of common stock sold in this offering will be available for sale in the public market, unless purchased by our affiliates or existing stockholders. Substantially all of our outstanding shares of common stock are currently restricted from resale as a result of “lock-up” agreements (which may be waived by BofA Securities, Inc. and Jefferies LLC with or without notice), as more fully described in “Shares Eligible for Future Sale.” These shares will become available to be sold 181 days after the date of this prospectus. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, and various vesting agreements.

After our initial public offering, certain of our stockholders will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders, subject to lockup agreements. We also intend to register shares of common stock that we have issued and may issue under our employee equity incentive plans. Once we register these shares, they will be able to be sold freely in the public market upon issuance, subject to existing market standoff or lock-up agreements.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

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.

Based upon shares outstanding as of June 30, 2020, prior to this offering, our executive officers, directors and the holders of more than 5% of our outstanding common stock, in the aggregate, beneficially owned

Table of Contents

approximately 96% of our common stock, and upon the completion of this offering, that same group, in the aggregate, will beneficially own approximately % of our common stock, assuming no purchases of shares in this offering by any members of this group, no exercise by the underwriters of their option to purchase additional shares, no exercise of outstanding options or warrants and after giving effect to the issuance of shares in this offering. 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, including those who purchase shares in this offering, 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.

We are an “emerging growth 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 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;
- 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) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least \$1.07 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 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.

Table of Contents

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

After the completion of this offering, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the other rules and regulations of the Securities and Exchange Commission, or 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 that we did not incur as a private company. 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.

After the completion of this offering, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Global Market, or Nasdaq. The Sarbanes Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Commencing with our fiscal year ending the year after this offering is completed, 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 in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to this offering, we have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

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

[Table of Contents](#)

subject to sanctions or investigations by the SEC or other regulatory authorities including equivalent foreign authorities.

We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with any certainty the particular uses of the net proceeds that we will receive from this offering, but we currently expect such uses will include funding our development of TP-03 for the treatment of Demodex blepharitis, and to develop our product pipeline, and other general corporate purposes, which may include the hiring of additional personnel, capital expenditures and the costs of operating as a public company. We will have broad discretion in the application of the net proceeds, including working capital and other general corporate purposes, and you and other stockholders may disagree with how we spend or invest these proceeds. The failure by our management to apply these funds effectively could adversely affect our business and financial condition. Pending their use, we may invest the net proceeds from our initial public offering in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

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. 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;

Table of Contents

- 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 impact of COVID-19; 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 that will be in effect at the completion of this offering could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Following the completion of this offering, 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 that will be in effect at the completion of this offering will 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 acquiror;
- 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;

Table of Contents

- 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.

For information regarding these and other provisions, see the section titled "Description of Capital Stock."

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum 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 will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us 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. These choice of forum provisions will not apply to claims arising under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other claim for which federal courts have exclusive jurisdiction.

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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, future revenue, business strategy, prospects, 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.

The words “anticipate,” “believe,” “contemplate,” “continue” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential” “predict,” “project,” “should,” “target,” “will” or “would” or the negative of these terms or other similar expressions are intended to identify forward looking statements. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- 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;
- 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 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 who suffer from Demodex blepharitis, MGD and rosacea 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;
- the timing or likelihood of regulatory filings and approval for 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;

Table of Contents

- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise;
- existing regulations and regulatory developments in the United States 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 this offering.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section titled “Risk Factors” elsewhere in this prospectus. 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 prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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 prospectus to conform these statements to actual results or to changes in our expectations.

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

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this prospectus from our internal estimates and research, including surveys and studies we have sponsored and/or conducted, and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. 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. Our estimates of the potential market opportunities for our product candidates include a number of key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. Information based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by us and third parties, industry, medical and general publications, government data and similar sources.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$ _____ million, or \$ _____ million if the underwriters exercise their option to purchase additional shares in full, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming an initial public offering price of \$ _____ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$ _____ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by approximately \$ _____ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The principal purposes of this offering are to increase our financial flexibility and create a public market for our common stock. We intend to use the net proceeds from this offering as follows:

- approximately \$ _____ million to fund our development of TP-03 for the treatment Demodex blepharitis; and
- the remaining proceeds to develop our product pipeline, and other general corporate purposes, which may include the hiring of additional personnel, capital expenditures and the costs of operating as a public company.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of our preclinical, clinical and future development activities may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from our ongoing and planned clinical trials, the timing of regulatory submissions and the outcome of regulatory review, our ability to take advantage of expedited programs or to obtain regulatory approval for product candidates, the timing and costs associated with the manufacture and supply of product candidates for clinical development or commercialization, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents, we estimate that such funds will be sufficient to enable us to _____ and fund our operating expenses and capital expenditure requirements through _____. We have based these estimates on assumptions that may prove to be wrong and we could use our capital resources sooner than we currently expect.

We may also use a portion of the net proceeds from this offering for the acquisition or in-license of other products, product candidates, businesses or technologies, although we have no current agreements or commitments for any material acquisitions or licenses of any products, businesses or technologies. Pending our use of the net proceeds from this offering, we plan to invest the net proceeds in a variety of capital preservation investments, including short-term interest-bearing investment-grade securities, certificates of deposit or government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our capital stock for the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to declare and pay dividends will be made at the discretion of our board of directors subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, business prospects, contractual restrictions, capital requirements and other factors our board of directors may deem relevant. Our future ability to pay cash dividends on our capital stock may also be limited by the terms of any future debt or preferred securities or any future credit facility.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and total capitalization as of June 30, 2020, as follows:

- on an actual basis;
- on a pro forma basis to reflect: (i) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of _____ shares of common stock; and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, each of which will occur immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to give effect to (i) the pro forma adjustments set forth above and (ii) the sale and issuance of _____ shares of our common stock by us in this offering, based upon the receipt by us of the estimated net proceeds from this offering at the assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. This information should be read in conjunction with our financial statements and the related notes appearing elsewhere in this prospectus, as well as the sections of this prospectus titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

(in thousands, except share and per share data)	As of June 30, 2020 (unaudited)		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
Cash and cash equivalents	\$ _____	\$ _____	\$ _____
Series A preferred stock, \$0.0001 par value per share; 11,698,716 shares authorized issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$ _____	\$ —	\$ —
Series B preferred stock, \$0.0001 par value; 50,000,000 shares authorized, and 49,578,623 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	—	—	
Stockholders’ (deficit) equity:			
Common stock, \$0.0001 par value; 103,000,000 shares authorized, _____ shares issued and outstanding, actual; _____ shares authorized, _____ shares issued and outstanding, pro forma; _____ shares authorized, _____ shares issued and outstanding, pro forma as adjusted			
Additional paid-in capital			
Accumulated deficit			
Total stockholders’ (deficit) equity	_____	_____	_____
Total capitalization	\$ _____	\$ _____	\$ _____

(1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders’ (deficit) equity and total capitalization by approximately _____.

Table of Contents

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

The number of shares of our common stock to be outstanding after this offering is based on shares of our common stock outstanding as of June 30, 2020 and excludes the following:

- shares of common stock issuable upon the exercise of options outstanding as of June 30, 2020, with a weighted-average exercise price of \$ per share;
- shares of common stock issuable upon the exercise of options granted after June 30, 2020, at a weighted-average exercise price of \$ per share;
- shares of common stock, legally issued upon the early exercise of certain stock options, but are subject to service conditions and the right of repurchase, that were outstanding as of June 30, 2020;
- shares of common stock reserved for future issuance under our 2016 Plan, as of June 30, 2020, which shares will be added to the shares to be reserved under our 2020 Plan upon its effectiveness;
- shares of common stock reserved for future issuance under our 2020 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- shares of common stock reserved for issuance under our 2020 ESPP, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

DILUTION

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

Historical net tangible book value (deficit) per share represents our total tangible assets less our liabilities and preferred stock that is not included in equity divided by the total number of shares of common stock outstanding. As of June 30, 2020, our historical net tangible book value (deficit) was approximately \$ _____ million, or \$ _____ per share of common stock. Our pro forma net tangible book value as of June 30, 2020, was approximately \$ _____ million, or \$ _____ per share of common stock, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of _____ shares of common stock immediately prior to the completion of this offering.

After giving further effect to receipt of the net proceeds of our sale of _____ shares of common stock at an assumed initial public offering price of \$ _____ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus and after deducting estimated underwriting discounts and commissions and estimated offering expenses, our pro forma as adjusted net tangible book value as of June 30, 2020 would have been approximately \$ _____ million, or \$ _____ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ _____ per share to our existing stockholders and an immediate dilution of \$ _____ per share to investors purchasing common stock in this offering. We determine dilution per share to new investors participating in this offering by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by investors participating in this offering.

The following table illustrates this dilution to new investors on a per share basis:

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of June 30, 2020	
Increase (decrease) in historical net tangible book value per share attributable to conversion of our preferred stock	
Pro forma net tangible book value (deficit) per share as of June 30, 2020	\$
Increase in pro forma net tangible book value per share attributable to new investors in this offering	\$
Pro forma as adjusted net tangible book value per share immediately after this offering	
Dilution per share to new investors purchasing shares in this offering	\$

If the underwriters' option to purchase additional shares in this offering is exercised in full, the pro forma as adjusted net tangible book value would be \$ _____ per share, the increase in the pro forma net tangible book value per share for existing stockholders would be \$ _____ per share and the dilution to new investors participating in this offering would be \$ _____ per share.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value, by \$ _____ per share and the dilution per share to new investors by \$ _____ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 shares in the number of shares we are offering would increase (decrease) our pro forma as adjusted net

Table of Contents

tangible book value by approximately \$ million, or \$ per share, and the pro forma dilution per share to investors in this offering by \$ per share, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma information discussed above is illustrative only and will change based on the actual initial public offering price, number of shares and other terms of this offering determined at pricing.

The table below summarizes, as of June 30, 2020, on a pro forma as adjusted basis, the number of shares of our common stock, the total consideration, and the average price per share (i) paid to us by our existing stockholders and (ii) to be paid by new investors participating in this offering at an assumed initial public offering price of \$ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Weighted-Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	<u>\$</u>
Existing stockholders		%	\$	%	\$
New investors					
Total		100%	\$	100%	

In addition, if the underwriters' option to purchase additional shares is exercised in full, the number of shares held by existing stockholders will be reduced to % of the total number of shares of common stock to be outstanding upon completion of this offering, and the number of shares of common stock held by new investors participating in this offering will be further increased to % of the total number of shares of common stock to be outstanding upon completion of the offering.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) total consideration paid by new investors by \$ and increase (decrease) the percent of total consideration paid by new investors by %, assuming the number of shares we are offering, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares offered by us would increase (decrease) total consideration paid by new investors by \$, assuming that the assumed initial price to the public remains the same, and after deducting the estimated underwriting discounts and commissions.

The number of shares of common stock to be outstanding after this offering is based on shares of common stock outstanding as of June 30, 2020 and excludes the following:

- shares of common stock issuable upon the exercise of options outstanding as of June 30, 2020 with a weighted-average exercise price of \$ per share;
- shares of common stock issuable upon the exercise of options granted after June 30, 2020 with a weighted-average exercise price of \$ per share;
- shares of common stock, legally issued upon the early exercise of certain stock options, but are subject to service conditions and the right of repurchase, that were outstanding as of June 30, 2020;

[Table of Contents](#)

- shares of common stock reserved for future issuance under our 2016 Plan, as of June 30, 2020, which shares will be added to the shares to be reserved under our 2020 Plan upon its effectiveness;
- shares of common stock reserved for future issuance under our 2020 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- shares of common stock reserved for issuance under our 2020 ESPP, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

To the extent that any outstanding options are exercised or new awards are granted under our equity compensation plans, new investors will experience further dilution.

SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements and related notes included elsewhere in this prospectus.

The statements of operations data for the years ended December 31, 2018 and 2019 and the balance sheet data as of December 31, 2018 and 2019 are derived from our audited financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future. The selected financial data in this section are not intended to replace our financial statements and the related notes and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2018	2019
	(in thousands, except share and per share amounts)	
Statement of Operations Data		
Operating expenses:		
Research and development	\$ 901	\$ 3,162
General and administrative	449	1,136
Total operating expenses	<u>1,350</u>	<u>4,298</u>
Loss from operations before other income (expense) and income taxes	<u>(1,350)</u>	<u>(4,298)</u>
Other income (expense):		
Interest income (expense), net	32	(40)
Loss on extinguishment of convertible notes	—	(255)
Change in fair value of derivative liabilities	—	(76)
Total other income (expense)	<u>32</u>	<u>(371)</u>
Provision for income taxes	<u>(1)</u>	<u>(1)</u>
Net loss	<u>\$ (1,319)</u>	<u>\$ (4,670)</u>
Net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	<u>\$ (0.10)</u>	<u>\$ (0.26)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	<u>13,068,854</u>	<u>17,728,991</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽¹⁾		<u>\$ (0.15)</u>
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽¹⁾		<u>32,008,512</u>

(1) For the calculation of our basic and diluted net loss per share, unaudited basic and diluted pro forma net loss per share and weighted-average number of shares used in the computation of the per share amounts, see Note 6 and Note 7 to our financial statements included elsewhere in this prospectus.

[Table of Contents](#)

	As of December 31,	
	2018	2019
	(in thousands)	
Balance Sheet Data		
Cash and cash equivalents	\$ 2,355	\$57,952
Working capital (1)	2,204	57,211
Total assets	2,389	58,316
Total liabilities	179	919
Preferred stock	3,564	63,402
Accumulated deficit	(1,364)	(6,034)
Total stockholders' deficit	(1,354)	(6,005)

(1) We define working capital as current assets less current liabilities as of the balance sheet date.

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 audited financial statements and the related notes to those statements included elsewhere in this prospectus. 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 those discussed under the section titled "Risk Factors" and elsewhere in this prospectus. See the section titled "Special Note Regarding Forward-Looking Statements" elsewhere in this prospectus.

Overview of our Business

We are a late clinical-stage biopharmaceutical company focused on the development and commercialization of first-in-class therapeutic candidates to address large market opportunities initially in ophthalmic conditions where there are limited treatment alternatives. Our lead product candidate, TP-03, is a Phase 3 ready, first-in-class, novel therapeutic being developed for the treatment of 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 a condition characterized by inflammation of the eyelid margin, redness and ocular irritation, including a specific type of eyelash dandruff called collarettes in Demodex blepharitis. The healthy interaction of the eyelid and the surface of the eyeball is crucial to ocular health. Poorly controlled and progressive blepharitis can lead to worsening of corneal damage over time and, in extreme cases, blindness. According to published studies, there are an estimated 20 million patients in the United States who suffer from blepharitis, with approximately 45% of cases caused by Demodex infestation. Further, our internal studies indicate the possibility that the number of Demodex blepharitis cases may be as high as approximately 25 million based on observation of collarettes in patients presenting to eye care clinics. We believe that, if approved, TP-03 has the potential to be the first FDA-approved therapeutic and become the standard of care for the treatment of Demodex blepharitis. To date, we have completed four Phase 2 trials for TP-03 in Demodex blepharitis, all of which showed highly statistically significant cure and eradication rates and TP-03 was well tolerated. We intend to commence our first Phase 3 trial, Saturn-1, in 2020 and a second Phase 3 trial, Saturn-2, in 2021 with primary and secondary endpoints consistent with those of the Phase 2 trials. If successful, we expect these trials to support the submission of an NDA, to the FDA for TP-03 for the treatment of Demodex blepharitis. Furthermore, we intend to pursue marketing authorizations in jurisdictions outside the United States, including Europe and Japan.

Our current therapeutic strategy is focused on the clinical development of, for the first time in human medicine, the novel drug, lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific GABA-Cl channels. Our pipeline will address a number of diseases across therapeutic categories including eye care and dermatology. These diseases include Demodex blepharitis, MGD and rosacea.

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 in November 2016, 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 and convertible promissory notes. From inception through December 31, 2019, we have raised net proceeds of approximately \$61.0 million through private placements of preferred stock.

Table of Contents

We have incurred significant net operating losses in every year since our inception and expect to continue to incur significant operating expenses and increasing operating losses for the foreseeable future. Our net losses were \$1.3 million and \$4.7 million for the years ended December 31, 2018 and 2019, respectively. Our net losses may fluctuate significantly from quarter to quarter and year to year and could be substantial. As of December 31, 2019, we had an accumulated deficit of \$6.0 million from research and development and general and administrative activities since our inception. We anticipate that our operating expenses will increase significantly as we:

- conduct additional clinical trials of our lead product candidate, TP-03, for the treatment of Demodex blepharitis including our Phase 3 trials, Saturn-1 and Saturn-2;
- advance the clinical development of TP-03 for the treatment of MGD and TP-04 for the potential treatment of rosacea;
- seek regulatory and marketing approvals for product candidates that successfully complete clinical development, if any;
- establish our own salesforce in the United States to commercialize our products for which we obtain regulatory approval;
- 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 have any products approved for sale and we have not yet generated any revenue from product sales or other sources. 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, 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, 2019, our aggregate cash and cash equivalents was \$58.0 million. We believe that the net proceeds from this offering together with our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the first half of 2020 – see “Liquidity and Capital Resources.”

Impact of the COVID-19 Pandemic on our Operations

Efforts to contain the spread of COVID-19 in the United States (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 an interim work-from-home 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. However, the ultimate effect from this pandemic on our development timelines for TP-03 and our other product candidates is inherently uncertain.

See “Risk Factors” for a further discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

In-License Agreement for Lotilaner

In January 2019, we entered into the Elanco Agreement with Elanco granting us worldwide development and marketing rights (including sublicense rights) to lotilaner for the treatment or cure of any eye or skin disease or condition in humans. We plan to utilize these license rights in developing and marketing our TP-03 and TP-04 product candidates.

We made an upfront payment of \$1.0 million to Elanco at contract execution, which we recorded within “research and development” expense within our statements of operations for the year ended December 31, 2019.

The value of remaining clinical milestone payments that may become contractually due to Elanco for the Demodex blepharitis or MGD indications aggregate \$3.0 million; and aggregate \$3.0 million for the rosacea indication. We may also be required to pay Elanco up to an aggregate of \$79.0 million for various commercialization milestones. Also, we will be obligated to pay Elanco tiered single-digit royalties on our worldwide net sales of these products.

Depending on the milestone type, upon achievement, we expect that we will either recognize the payment value within “research and development” expense or “cost of sales” in our consolidated statements of operations. Ongoing royalty payments will be recognized within “cost of sales” in our consolidated statements of operations. The corresponding liability for any payment due to Elanco will be recognized within “accounts payable and other accrued liabilities” in our consolidated balance sheets in the earliest period that we determine the respective payment is triggered or becomes probable.

Components of our Results of Operations

Operating Expenses

Our operating expenses since inception have consisted solely of research and development expenses and general and administrative expenses.

Research and Development Expenses

Our 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 specific tasks or patient dosing using information provided to us by our service providers.

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 track our internal research and development expenses on a program-by-program basis as they primarily relate to compensation, early research and other costs which are deployed across multiple projects under development. For the years ended December 31, 2018 and 2019, substantially all of our research and development expenses are attributable to our TP-03 program for Demodex blepharitis.

Research and development activities are central to our business model. Product candidates in later stages of clinical development, such as TP-03, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase substantially following this offering and 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 and TP-04 for the potential treatment of rosacea, complete our clinical programs, pursue regulatory approval of our product candidates, and prepare for the possible commercialization of these product candidates. The successful development of our product candidates is highly uncertain. As this time, we cannot precisely estimate the aggregate costs required to complete significant portions of our clinical programs or additional costs associated with the validation of our contract manufacturers and suppliers as required by the FDA. See “Risk Factors” for a discussion of risks and uncertainties associated with our research and development projects.

General and Administrative Expenses

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

[Table of Contents](#)

We expect that our general and administrative expenses will increase substantially in the future as a result of expanding our operations, including hiring personal, 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 consists primarily of interest expense on our convertible promissory notes, other expense from the change in fair value of the derivative liabilities associated with the promissory notes and losses recorded on the extinguishment of convertible promissory notes. Interest expense is comprised of coupon interest, amortization of debt issuance costs, and non-cash accretion of an estimated discount on the convertible promissory notes (as part of the separate recognition of an embedded derivative liability). Our recognized interest expense was partially offset by interest income earned on our cash and cash equivalents.

Income Tax 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 of December 31, 2019, we had deferred tax assets including federal and state net operating loss carryforwards of \$1.3 million. 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, 2018 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. At December 31, 2019, we had federal and California research and development tax credits of \$0.1 million each. The federal research and development tax credits begin to expire in 2037 unless previously utilized, and the California credit carryforwards are available indefinitely.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2019

The following table summarizes our results of operations for the years ended December 31, 2018 and 2019 (in thousands):

	Year Ended December 31,		Change	% Change
	2018	2019		
			(in thousands)	
Operating expenses:				
Research and development	\$ 901	3,162	2,261	251%
General and administrative	449	1,136	687	153
Total operating expenses	1,350	4,298	2,948	218
Loss from operations before other income (expense) and income taxes	(1,350)	(4,298)	(2,948)	(218)
Other income (expense):				
Interest income (expense), net	32	(40)	(72)	(225)
Loss on extinguishment of convertible notes	—	(255)	(255)	(100)
Change in fair value of derivative liabilities	—	(76)	(76)	(100)
Total income (expense), net	32	(371)	(403)	(1,259)
Provision for income taxes	(1)	(1)	—	—
Net loss	<u>\$ (1,319)</u>	<u>\$ (4,670)</u>	<u>\$ (3,351)</u>	<u>(254)%</u>

[Table of Contents](#)

Research and Development Expenses

Research and development expenses increased by \$2.3 million for the year ended December 31, 2019. The increase was primarily due to (i) our one-time upfront payment of \$1.0 million for the lotilaner in-license, (ii) increased payroll and personnel related expenses (including stock-based compensation) of \$0.9 million due to additional clinical and formulation development employees to drive our product development initiatives, and (iii) increased clinical study site costs of \$0.3 million.

General and Administrative Expenses

General and administrative expenses increased by \$0.7 million for the year ended December 31, 2019. The increase was primarily due to \$0.5 million increase in payroll and personnel-related expenses (including stock-based compensation) for employee additions and \$0.2 million increase primarily from legal costs and market research activities.

Interest Income (Expense), Net

The change in interest income (expense), net was primarily due to convertible promissory notes issued to our co-founders and certain other related parties, aggregating \$2.0 million in principal value (see below). During the year ended December 31, 2019 interest expense recognized for these notes was \$0.1 million and was partially offset by interest income on our cash and cash equivalents.

Change in Fair Value of Derivative Liabilities

During May, August, and October 2019, we issued convertible promissory notes to our co-founders and certain other related parties, aggregating \$2.0 million in principal value. These notes contained stock-settled redemption features that were required to be separately accounted for as derivative liabilities on the balance sheet until December 13, 2019 when we completed a qualified equity financing and these then-outstanding notes converted at the option of the holder into 2.0 million shares of Series B Preferred Stock. Change in fair value of derivative liabilities consists of non-cash changes in the fair value of these stock-settled redemption features. We classified the rights as a derivative liability on our balance sheet that was initially recorded at fair value and that we remeasured to fair value at December 13, 2019, and we recognized changes in the fair value of the derivative associated with the rights as a component of other income (expense) in our statement of operations.

Loss on Extinguishment of Convertible Notes

The loss on extinguishment of convertible notes was due to the extinguishment of convertible promissory notes issued to our co-founders and certain other related parties, aggregating \$2.0 million in principal value (see below). On December 13, 2019 we completed the issuance of Series B Preferred Stock upon which the then-outstanding notes, along with accrued interest, converted into 2.0 million shares of Series B Preferred Stock.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2016 through December 31, 2019, our operations have been substantially financed by net cash proceeds of \$61.0 million from private placements of Series A and Series B preferred stock. We will continue to be dependent upon equity, debt financing, and/or other forms of capital raises at least until we are able to generate significant positive cash flows from our operations. As of December 31, 2019, we had cash and cash equivalents of \$58.0 million. We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

Funding Requirements

Our primary use of cash is to fund operating expenses, consisting of research and development expenditures (including clinical and regulatory activities) and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay or prepay for these activities.

We believe that the net proceeds from this offering together with our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the _____ of 202 . We have based these estimates on our current assumptions that may require subsequent adjustment based on our ongoing business decisions. Accordingly, we may require additional capital resources sooner than we currently expect.

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we (1) complete development of any of our product candidates; (2) obtain applicable regulatory approval; and (3) successfully commercialize or enter into collaborative agreements for such product candidates. We do not know when, or if, any of these items will ultimately occur. We expect to continue to incur significant losses for the foreseeable future and we expect our losses to increase as we continue these activities. We may encounter unforeseen expenses, difficulties, complications, delays and other currently unknown factors that may adversely affect our business. Moreover, following the completion of this offering, we expect to incur additional costs associated with operating as a public company.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We anticipate that we will need to raise substantial additional capital, the requirements for which 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;
- 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;

[Table of Contents](#)

- our implementation of various computerized information systems;
- impact of 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 of our 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 prospectus titled “Risk Factors” for additional risks associated with our substantial capital requirements.

Convertible Notes

From May 2019 through October 2019, we issued convertible promissory notes with an aggregate principal amount of \$2.0 million. These notes were fully converted into an aggregate of 1,991,052 shares of Series B Preferred Stock in December 2019.

Summary Statement of Cash Flows

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

	Year Ended December 31,	
	2018	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$(1,183)	\$(3,673)
Investing activities	(7)	(175)
Financing activities	3,564	59,445
Net increase in cash, cash equivalents and restricted cash	<u>\$ 2,374</u>	<u>\$55,597</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was \$1.2 million for the year ended December 31, 2018, which was primarily due to our net loss of \$1.3 million, partially offset by an increase in accrued liabilities of \$0.1 million associated with clinical and manufacturing activities.

[Table of Contents](#)

Net cash used in operating activities was \$3.7 million for the year ended December 31, 2019, which primarily consisted of our net loss of \$4.7 million, partially offset by non-cash items totaling \$0.5 million and a net increase in liabilities of \$0.5 million associated with accounts payable and accrued bonuses.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$7 thousand for the year ended December 31, 2018, which consisted of property and equipment purchases.

Net cash used in investing activities was \$0.2 million for the year ended December 31, 2019, which consisted of property and equipment purchases and tenant improvements to our leased laboratory and administrative offices.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$3.7 million for the year ended December 31, 2018 due to our issuance of Series A preferred stock.

Net cash provided by financing activities was \$59.4 million for the year ended December 31, 2019 due to our issuance of Series B preferred stock for net proceeds of \$57.5 million and issuance of convertible promissory notes for proceeds of \$2.0 million.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019:

	Payments Due by Period				Total
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	
Operating lease obligations (1)	\$ 77	\$ 106	\$ —	\$ —	\$ 183
Contingent milestone obligations (2)	\$2,000	\$6,000	\$ 11,000	\$ 66,000	\$ 85,000

(1) The operating lease obligations are related to the facility lease for our corporate headquarters and research and development facility in Irvine, California, expiring April 30, 2022.

(2) Milestone obligations are contingent upon our achievement of specified development, regulatory and sales milestones. Given the unpredictability of the drug development process, and the impossibility 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 in-license agreement with Elanco are successfully met. These values in each column represent the composite best estimates for each achievement date. In the event that any or all of these milestones are met, we believe that the corresponding increase in value from the related drug product will exceed the amount of the milestone obligation.

We enter into contracts in the normal course of business with clinical research consultants and clinical sites and with contract manufacturers for pre-clinical and clinical drug supply, as well as with various other vendors in operating our business. These contracts generally provide for termination provisions with notice, and therefore we believe that our non-cancelable obligations under these agreements were not material as of December 31, 2019.

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, or GAAP. The preparation of these financial statements requires us to make estimates and

Table of Contents

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 registration statement, we believe these critical accounting policies are the most important to understanding and evaluating our reported financial results.

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. These expenses also include internal costs directly attributable to in-development programs, including cost of certain salaries, payroll taxes, employee benefits, and stock-based compensation expense, as well as laboratory and clinical supplies, pre-clinical and clinical trial related expenses, and the cost of services provided by outside contractors.

We have entered, and may continue to enter into, license agreements to access and utilize certain technology. In each case, we evaluate if the assets acquired in a transaction represent the acquisition of an asset or a business, as defined under applicable GAAP. Our only executed in-license agreement was evaluated and determined to represent an asset acquisition. Because this asset had not yet received regulatory approval and has no alternative future use, its fair value was immediately recognized as research and development expense.

We make research and development expense accrual estimates as of each balance sheet date, based on facts known to us at that time. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We periodically confirm the accuracy of our estimates with the service providers, including CROs, and record adjustments, if necessary. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation

We measure and recognize compensation expense for all options based on the estimated fair value of the award on the grant date. We use the Black-Scholes option-pricing model to estimate the fair value of awarded stock options. The fair value is recognized as expense on a straight-line or ratable basis over the requisite or implicit service period.

The determination of the grant date fair value of options using an option pricing model is affected principally by our estimated fair value of shares of our common stock and requires management to make a number of other assumptions, including the (a) the fair value of Tarsus common stock on the date of the option grant, (b) the expected term of the stock option until its exercise by the recipient, (c) our stock price volatility over the expected term, (d) the prevailing risk-free interest rate over the expected term, and (e) our expected dividend payments over the expected term.

The assumptions used in our Black-Scholes option-pricing model represent management's best estimates at the time of measurement. These estimates are complex and involve a number of variables, uncertainties, and assumptions and the application of management's judgment. If any assumptions change, our stock-based compensation expense could be materially different in the future.

Fair Value of Common Stock

We are required to periodically estimate the fair value of our common stock in order properly apply the Black-Scholes option pricing model to value our issued stock options to employees, board members, and consultants. The fair value of our common stock is the most subjective input into this option pricing model. The fair value of our common stock underlying our stock-based awards at the time of issuance was derived with the assistance of an independent and qualified valuation expert. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, the estimated fair value of our common stock has been determined by our board of directors, with input from management, taking into consideration our most recently available third-party valuations of our common stock at the time of the grants, as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation report through the date of the grant. Third-party valuations, or valuation reports, were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' *Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid*.

In addition to contemporaneous third-party valuation reports, our board of directors also considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:

- the price of our Series A preferred stock and Series B preferred stock sold to investors in arm's length transactions and the rights, preferences and privileges of such preferred stock as compared to those of our common stock, including the liquidation preferences of such preferred stock;
- our results of operations, financial position and the status of research and development and clinical development efforts and achievement of enterprise milestones;
- the composition of, and changes to, our management team and board of directors;
- the lack of liquidity of our common stock as a private company;
- our stage of development, business strategy and the material risks related to our business and industry;
- the valuation of publicly-traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- external market conditions affecting the life sciences and biotechnology industry sectors;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering, or IPO, or a sale of our company, given prevailing market conditions; and
- the state of the IPO market for similarly situated privately held biotechnology companies.

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

- Hybrid Option Pricing Method. Under the hybrid option pricing method, or OPM, shares are valued by taking into account the preferred stockholders' liquidation preferences, participation rights, dividend policy, and conversion rights to determine how proceeds from a liquidity event shall be distributed among the various ownership classes at a future date.

Table of Contents

- **Probability-Weighted Expected Return Method.** The probability-weighted expected return method, or PWERM, is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

Based on our early stage of development and other relevant factors, we determined that an OPM was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock for the valuation performed on May 31, 2018. For the valuation performed after this date which valued our common stock as of March 19, 2020, we also used an OPM method to determine the estimated fair value of our common stock. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

The 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.

Once a public trading market for our common stock has been established in connection with the closing of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the daily quoted market price of our common stock.

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 also included in this registration statement.

Off-Balance Sheet Arrangements

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

Indemnification Agreements

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, 2019.

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 this offering, (b) in which we have total annual gross

[Table of Contents](#)

revenues of at least \$1.07 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.

Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of December 31, 2019, we had cash and cash equivalents of \$58.0 million, consisting of interest-bearing money market accounts, for which the fair market value would be affected by changes in the general level of United States interest rates. However, due to the short-term maturities and the low-risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash and cash equivalents.

We do not believe that inflation, interest rate changes, or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

BUSINESS

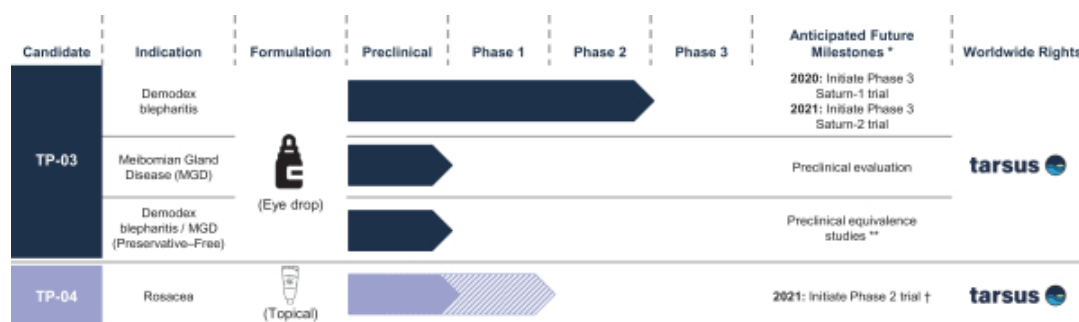
Overview

We are a late clinical-stage biopharmaceutical company focused on the development and commercialization of first-in-class therapeutic candidates to address large market opportunities initially in ophthalmic conditions where there are limited treatment alternatives. Our lead product candidate, TP-03, is a Phase 3 ready, first-in-class, novel therapeutic being developed for the treatment of 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 a condition characterized by inflammation of the eyelid margin, redness and ocular irritation, including a specific type of eyelash dandruff called collarettes in Demodex blepharitis. The healthy interaction of the eyelid and the surface of the eyeball is crucial to ocular health. Poorly controlled and progressive blepharitis can lead to worsening of corneal damage over time and, in extreme cases, blindness. According to published studies, there are an estimated 20 million patients in the United States who suffer from blepharitis, with approximately 45%, or approximately 9 million, of cases caused by Demodex infestation. Further, our internal studies indicate the possibility that the number of Demodex blepharitis cases may be as high as approximately 25 million based on observation of collarettes in patients presenting to eye care clinics. To date, we have completed four Phase 2 trials for TP-03 in Demodex blepharitis, all of which showed highly statistically significant cure and eradication rates and TP-03 was well tolerated. We intend to commence our first Phase 3 trial, Saturn-1, in 2020 and a second Phase 3 trial, Saturn-2, in 2021 with primary and secondary endpoints consistent with those of the Phase 2 trials. If successful, we expect these trials to support the submission of an NDA to the FDA for TP-03 for the treatment of Demodex blepharitis. Furthermore, we intend to pursue marketing authorizations in jurisdictions outside the United States, including Europe and Japan. We believe that, if approved, TP-03 has the potential to be the first FDA-approved therapeutic and become the standard of care for the treatment of Demodex blepharitis.

Our current therapeutic strategy is focused on the clinical development of, for the first time in human medicine, the novel drug, lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific GABA-Cl channels. We are advancing our pipeline to address a number of diseases across therapeutic categories including ophthalmic conditions, and dermatology. These diseases include Demodex blepharitis, MGD and rosacea.

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

Figure 1: Pipeline Chart



* Anticipated milestones are subject to the impact of the ongoing COVID-19 pandemic on our business.

** We intend to initiate preclinical equivalence studies with our preservative-free formulation of TP-03 in Demodex blepharitis after NDA submission of the original formulation of TP-03 in Demodex blepharitis.

† We intend to initiate a Phase 2 trial exploring TP-04 in Rosacea without first conducting Phase 1 trials.

Blepharitis: A Significant, Underserved & Underdiagnosed Market

Blepharitis is a common, chronic ophthalmic condition 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, in extreme cases, blindness. According to published studies, estimated 20 million patients suffer from blepharitis, and there is growing recognition within the ophthalmic community about Demodex mites as an underlying cause of blepharitis. Demodex mites are the most common ectoparasite found on humans. Demodex mites potentially cause approximately 45% of blepharitis cases, or approximately 9 million patients. Based on our internal studies of collarette prevalence in the eye care office, we believe that the number of Demodex blepharitis patients in the United States may be as high as approximately 25 million. In addition, there is growing awareness among ECPs of a specific type of debris found at the base of the eyelashes, known as collarettes, or cylindrical dandruff, which are highly correlated with Demodex infestation. 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. Demodex blepharitis increases progressively with aging, which is the main risk factor for the condition. These patients commonly present to the offices of ECPs for other ophthalmic conditions besides blepharitis, such as cataract surgery 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 condition in standard practice.

Despite the high prevalence of patients with Demodex blepharitis and growing awareness of the condition amongst ECPs, there are no FDA-approved therapeutics for the treatment of blepharitis or for Demodex blepharitis. Although we believe blepharitis and Demodex blepharitis are significantly underdiagnosed conditions, with limited treatment alternatives, there are already an estimated 2.1 million annual blepharitis diagnoses in the United States. 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 lead to significant irritation and dissatisfaction for patients, and do not eradicate the Demodex mites.

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 indicative of Demodex blepharitis, further validating the accessible opportunity to increase diagnosis rates amongst patients. In addition, our market research suggests the potential for a high level of adoption of TP-03, if approved. In our surveys, we interviewed 50 ECPs, 96% of whom indicated they would prescribe TP-03 as a first-line treatment for Demodex blepharitis after exposure to the TP-03 target product profile. Since patients continue to have underlying risk of Demodex infestation, there could be a recurrence based on the presence of Demodex mites in the skin even after eradication of Demodex mites from the eyelid as demonstrated in our Phase 2 trials with TP-03. Our Phase 2 data from the Mars and Jupiter clinical trials followed patients to one year after treatment and showed meaningful recurrence of Demodex blepharitis within six to nine months, which increased considerably one year after treatment. We believe this data suggests TP-03, if approved, may be used on a chronic, intermittent basis in Demodex blepharitis.

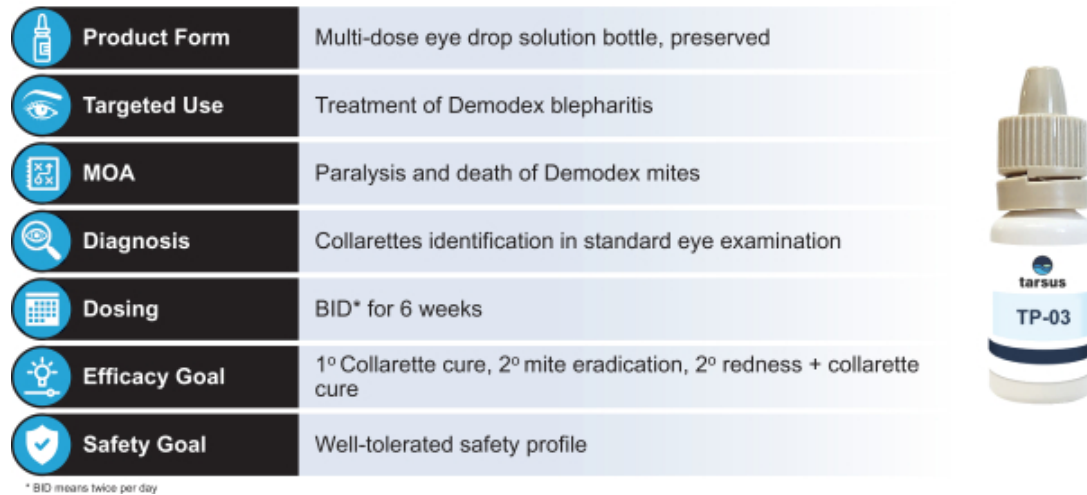
We believe the blepharitis market has the potential to be analogous to other ophthalmic markets that grew significantly once there was a product to address the large, latent demand for an effective therapy. Another ocular surface disease, dry eye, had no approved therapeutic for the condition until 2003. With the approval of Allergan's Restasis (cyclosporine) in 2003 and concurrent ECP and patient education, the diagnosis rate increased by approximately 12x, growing from 500,000 diagnoses in 2003 to over 6 million diagnoses in 2015. Annual diagnoses rates have been maintained at similar levels since 2015, and in 2016 Restasis generated peak revenue of \$1.5 billion. Blepharitis already has 2.1 million diagnoses per year, despite no approved therapies to help with market awareness, but like dry eye, we believe there is potential for significant market expansion. We believe there is a significant opportunity to increase the diagnosis rate of Demodex blepharitis and build a significant new market with the approval of a safe and effective therapeutic alternative that addresses the underlying cause of the condition.

Our Approach: TP-03

There are currently no FDA-approved therapeutics for blepharitis, which remains a significant unmet need for patients. 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 first-in-class therapeutic based on the novel drug, lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific GABA-Cl channels.

The following figure provides the characteristics of TP-03 in the Saturn-1 Phase 3 clinical trial:

Figure 2: Characteristics of TP-03 in the Saturn-1 Phase 3 Clinical Trial



We have completed four Phase 2 clinical trials to date, along with one additional *ex vivo* study. Key efficacy endpoints included cure rate based on collarette grade, which we refer to herein as collarette cure rate and mite eradication rate, with TP-03 meeting its primary and secondary endpoints and showing highly statistically significant cure and eradication rates in our two most recent trials, Io and Europa. TP-03 was generally well tolerated throughout these trials.

The results of our Phase 2 trials highlight the robust and consistent clinical efficacy of TP-03 in curing collarettes and eradicating mites which we believe are essential to successfully treat Demodex blepharitis. The Phase 2a Mars trial was a smaller single arm study evaluating the safety and efficacy of TP-03 with a 28-day BID dosing regimen, exploratory endpoints including collarette grading score and mite density. We utilized the data from the exploratory endpoints to determine collarette cure rate, defined as 10 or fewer collarettes, and mite eradication rate, defined as zero mites per lash. Both collarette cure and mite eradication rates were assessed at 28 days, which were 86% and 57% respectively. The Phase 2b Jupiter trial was a larger randomized, controlled double-blind trial with collarette grade and mite density as primary and secondary endpoints, respectively. Similarly to the Mars trial, we utilized the collarette grading and mite density data to determine collarette cure and mite eradication rates, which were both defined consistently with those used in the Mars trial. The efficacy observed in the Jupiter trial appeared consistent with the Mars trial, with a collarette cure rate of 88%, and mite eradication rate of 66%, which were statistically significant compared to the vehicle control. We subsequently conducted the Io Phase 2a and Europa Phase 2b trials to evaluate the safety and efficacy of TP-03 formulation for the treatment of Demodex blepharitis. The design of the Io trial took into account feedback from the FDA, and accordingly we defined collarette cure rate to a more stringent definition of two or fewer collarettes on the eyelid and mite eradication rates, with a treatment duration of 42 days. In the Io trial, we utilized for the first time in clinical studies the formulation of TP-03 that is expected to support our NDA submission for Demodex

blepharitis. The key differences between the Io and Europa trials, were that Io was a smaller single-arm trial, while Europa was slightly larger randomized placebo-controlled trial. The observed efficacy in Io and Europa were consistent across both studies, with a collarette cure rate of 72% and 79% respectively, and a mite eradication rate of 78% and 71% respectively. The meaningful and consistent clinical efficacy and safety results we observed across our comprehensive Phase 2 program, provided us with the basis to design and initiate our pivotal Phase 3 program.

The following figure provides a summary of our completed and planned clinical investigations evaluating TP-03 for Demodex blepharitis:

Figure 3: Our Completed and Planned Clinical Investigations

Trial / Study	Design	Objectives	Results	Status	
PoC: Mercury	Ex-vivo mite testing on 80 mites	Ex-vivo mite death count	100% mites dead within 24 hours (p < 0.001)		
Clinical Trials			Collarette Cure Rate***	Mite Eradication Rate	
P2a: Mars *	28-day BID dosing, single arm (n=15) Pilot formulation	Collarette grade Mite density Safety	86% at 28 days (p < 0.05)	57% at 28 days (p < 0.05)	
P2b: Jupiter *	28-day BID dosing, randomized 1:1 (n=60) Pilot formulation	1° – Collarette grade 2° – Mite density Safety	88% at 28 days (p < 0.001)	67% at 28 days (p < 0.005)	
P2a: Io	42-day BID dosing, single arm (n=18) Current formulation	1° – Collarette cure 2° – Mite eradication Safety	72% at 42 days (p < 0.05)	78% at 42 days (p < 0.05)	
P2b: Europa	42-day BID dosing, randomized 1:1 (n=54) Current formulation	1° – Collarette cure 2° – Mite eradication 2° – Redness Composite Safety	80% at 42 days (p < 0.001)	73% at 42 days (p = 0.003)	
P3: Saturn-1	42-day BID dosing, randomized 1:1 (n=350) Current formulation **	1° – Collarette cure 2° – Mite eradication 2° – Redness Composite Safety	Initiate trial in 2020		
P3: Saturn-2	42-day BID dosing, randomized 1:1 (n=350) Current formulation **	1° – Collarette cure 2° – Mite eradication 2° – Redness Composite Safety	Initiate trial in 2021		

* The Mars and Jupiter trials used collarette grade as an endpoint, which has been translated into a collarette cure (defined as <10 collarettes). This is different from the collarette cure (defined as <2 collarettes) endpoint used in Io, Europa and the planned Saturn-1/2 trials. Mite density is translated into mite eradication, which is defined as 0 mites consistently throughout trials.

** Expected design pending FDA feedback.

*** Primary endpoint in Io, Europa, and intended in Saturn-1 and Saturn-2, is cure based on collarette grade.

Represents pivotal trial Same endpoints and formulation of TP-03 as Saturn trials

We plan to evaluate TP-03 in two Phase 3 pivotal registration trials, referred to as Saturn-1 and Saturn-2. Saturn-1 is a Phase 3, randomized, controlled, double-blind trial to evaluate the safety and efficacy of TP-03 in approximately 350 Demodex blepharitis patients in multiple centers in the United States. Enrollment of Saturn-1 is expected to begin in 2020 and top-line data is expected in 2021, subject to the impact of the ongoing COVID-19 pandemic. Saturn-2, our confirmatory Phase 3 randomized, controlled, double-blind trial, has a highly comparable design to that of Saturn-1 and is also expected to enroll approximately 350 Demodex blepharitis patients. Enrollment of Saturn-2 is expected to begin in 2021, subject to the impact of the ongoing COVID-19 pandemic. We expect these trials to support the potential submission of an NDA for TP-03 for the treatment of Demodex blepharitis.

We also intend to explore the therapeutic potential of TP-03 for a second ophthalmic condition, MGD, commonly characterized in part by a widespread clogging of the meibomian glands that 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 United States, MGD prevalence has been found to be approximately two-thirds of that 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

[Table of Contents](#)

Demodex brevis. TP-03 is designed to relieve some of the key elements of MGD by virtue of causing the death of the *Demodex brevis* mites.

Beyond TP-03, we are developing TP-04 for the potential treatment of rosacea, a condition that affects approximately 16 million patients per year in the United States.

Our Strengths and Differentiation

We believe our company and our product candidates have the following key distinguishing characteristics:

- **Compelling efficacy and safety data.** We have observed TP-03's compelling efficacy and safety in our four Phase 2 clinical trials – Mars, Jupiter, Io, and Europa – where treatment with TP-03 resulted in highly statistically significant levels of collarette cure rate and mite eradication rate and was well tolerated. Our Phase 3 trials, Saturn-1 and Saturn-2, are expected to utilize trial designs that are highly comparable to those of the Phase 2 Io and Europa trials.
- **Large, underserved and underdiagnosed blepharitis market with a significant opportunity for growth.** Although we believe blepharitis and Demodex blepharitis are significantly underdiagnosed conditions, with limited treatment alternatives, there are already an estimated 2.1 million annual blepharitis diagnoses in the United States. However, we believe the market opportunity may be substantially larger. According to published studies, there are an estimated 20 million patients in the United States that suffer from blepharitis with approximately 45% of cases caused by Demodex infestation. Further, our internal studies indicate the possibility that the number of Demodex blepharitis cases may be as high as approximately 25 million based on observation of collarettes in patients presenting to eye care clinics. We believe the blepharitis market has the potential to be analogous to other ophthalmic markets where diagnoses grew significantly once there was a product to address the large, latent demand for an effective therapy, as was observed with the approval of Allergan's Restasis in 2003.
- **Novel chemistry developed for the first time in human medicine.** Our current therapeutic strategy is focused on the clinical development of, for the first time in human medicine, the novel drug, lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific GABA-Cl channels. Our pipeline aims to address a number of diseases across therapeutic categories including ophthalmic conditions and dermatology.
- **Additional opportunities beyond Demodex blepharitis.** Like blepharitis, MGD may also be caused by Demodex infestation, and we intend to explore the therapeutic potential for TP-03 in this indication. In the United States, MGD prevalence has been found to be approximately two-thirds of that of the estimated 34 million dry eye patient population. Further, we are developing TP-04 for the potential treatment of rosacea, a condition that affects approximately 16 million patients per year in the United States.
- **Experienced management team and board of directors supported by high quality investor base.** We have built a leadership team with significant experience in developing and commercializing therapeutic products for ophthalmic conditions. Members of our management team and board of directors have founded and led several biopharmaceutical companies including those in the ophthalmic care space, such as Oyster Point Pharma and Oculeve, and have been pivotal in the development and commercialization of various leading ophthalmic products, including the dry eye therapy, Restasis.

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 through clinical development and eventual approval for the treatment of Demodex blepharitis.** We have observed in multiple Phase 2 trials across 147 patients that TP-03 results in collarette cure and mite eradication, the same clinical endpoints that will be utilized in our pivotal Phase 3 trials. We expect enrollment of our first pivotal trial, Saturn-1, to begin in 2020 and top-line data is anticipated in 2021, subject to the impact of the ongoing COVID-19 pandemic. Enrollment of our second pivotal trial, Saturn-2, is expected to begin in 2021, subject to the impact of the ongoing COVID-19 pandemic.
- **Educate ECPs and establish our own specialty sales organization to commercialize TP-03 in the United States.** 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 25,000 prescribing ECPs in the United States. Throughout our commercialization efforts, we intend to educate ECPs on Demodex blepharitis and how to diagnose it with a simple slit lamp examination. We have completed an in-depth claims analysis and market research studies that have demonstrated a significantly prevalent Demodex blepharitis population and the importance of educating ECPs on the key role of collarettes in diagnosing Demodex blepharitis. Outside the United States, we intend to establish commercialization strategies for TP-03 as we approach possible commercial approval in each market, which may include collaborations with other companies.
- **Expand the label of TP-03 for other indications and develop our pipeline to bring a novel, first-in-class, anti-parasitic molecule to unmet needs across human medicine, including rosacea.** Like blepharitis, MGD may also be caused by Demodex infestation, and we intend to explore the therapeutic potential for TP-03 in the indication. Further, we plan to expand our pipeline of novel, differentiated products that target parasites to treat diseases with large market opportunities, like rosacea. The lotilaner mechanism of action coupled with our insights into disease where it can demonstrate clinical benefit provides an opportunity to expand into new indications for treatment. By utilizing new formulations of lotilaner, we intend to create cream formulations designed to treat rosacea.
- **Evaluate and selectively enter into strategic partnerships to maximize the potential of our pipeline and the scope of our eye care product offerings.** We have retained our rights globally to all of our indications for use in humans. Given the potential to treat patients worldwide we may opportunistically enter into strategic partnerships around certain product candidates, disease or geographic regions. These collaborations could help expand and accelerate our programs to maximize their worldwide market potential, especially in regions where a partner may bring greater expertise or resources.

Blepharitis Overview

Blepharitis

Ocular surface disease represents a broad category of disease that affects at least 35 million people in the United States. The ocular surface comprises the cornea, conjunctiva, eyelids and lacrimal glands and as such any diseases in these structures can be classified as ocular surface disease. Common ocular surface diseases include dry eye disease, ocular allergy, blepharitis and MGD. Almost all of the ocular surface diseases are associated with eye redness and ocular surface inflammation and in some cases conjunctival and/or lid edema. Patients often present with multiple ocular surface diseases and the symptoms have significant overlap, leading to frequent misdiagnosis of the various conditions.

Blepharitis is a common chronic ophthalmic condition characterized by inflammation of the eyelid margin, redness and ocular irritation. Based on published studies, an estimated 20 million patients suffer from blepharitis. Typical signs and symptoms of blepharitis include debris on the eyelashes, redness of eye and eyelid, missing or misdirected eyelashes, blurring of vision, irritation, itchiness and ocular discomfort. It 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 in extreme cases, blindness. Blepharitis can limit the ability for patients to tolerate contact lenses and may impact patient satisfaction with cataract and refractive surgery, all of which lead to lower quality of life and poor vision. Blepharitis is primarily diagnosed and treated by ECPs, including ophthalmologists and optometrists.

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

The following image shows an eyelid with blepharitis:

Figure 4: Eyelid With Blepharitis



Demodex Blepharitis

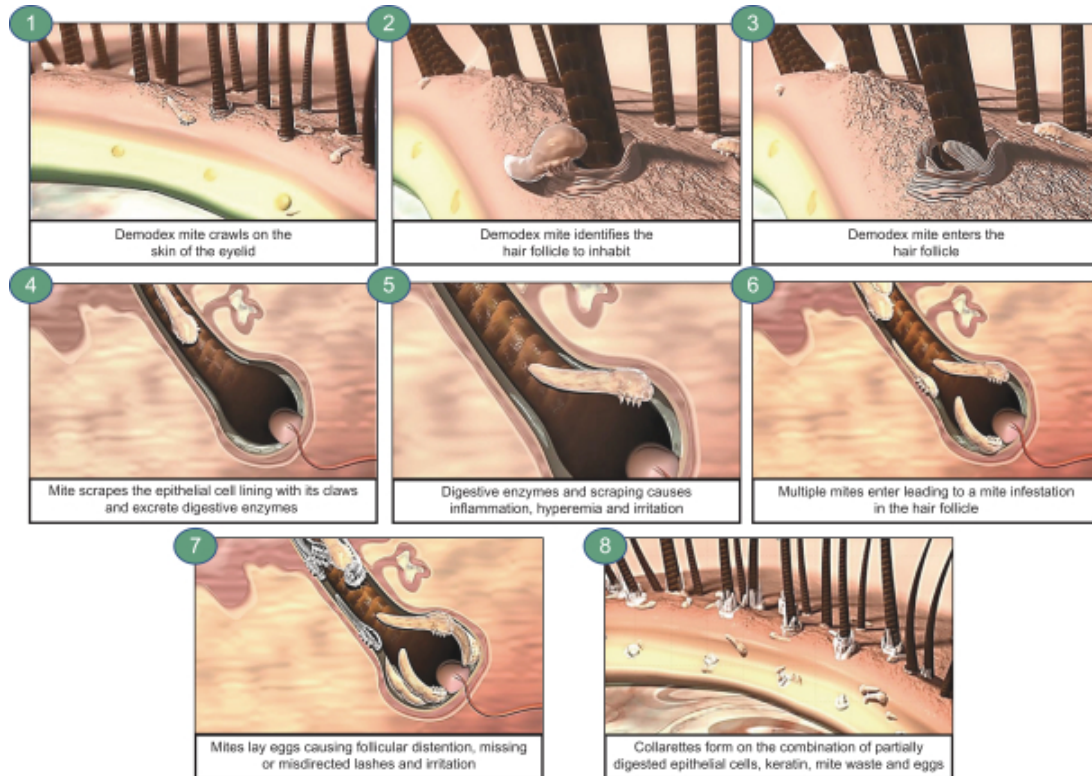
Demodex infestation is a major cause of blepharitis, implicated in approximately 45% of blepharitis cases, or approximately 9 million patients. Based on our internal studies of collarette prevalence in the eye care office, we believe that the number of Demodex blepharitis patients in the United States may be as high as approximately 25 million. These blepharitis cases are referred to Demodex blepharitis. 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 condition. 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 key clinical 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 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, in extreme cases, blindness. Furthermore, Demodex blepharitis can negatively impact quality of life and create an emotional burden for individuals with the condition.

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

Figure 5: *Demodex folliculorum* Mites Entering and Residing in Eyelash Follicles



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

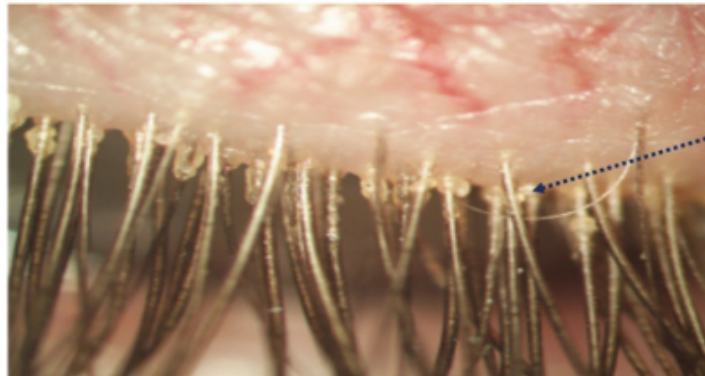
- 1) **Mechanical:** Overcrowded mites scrape the epithelial cell lining of the eyelash follicles with their claws and lay eggs, causing follicular distention, misdirected lashes, eyelash loss and irritation. Dead mites and collarettes also obstruct the hair follicle opening, leading to inflammation.
- 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 cause inflammation of the surrounding ocular tissues.

[Table of Contents](#)

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 shows collarettes at the base of an eye lash:

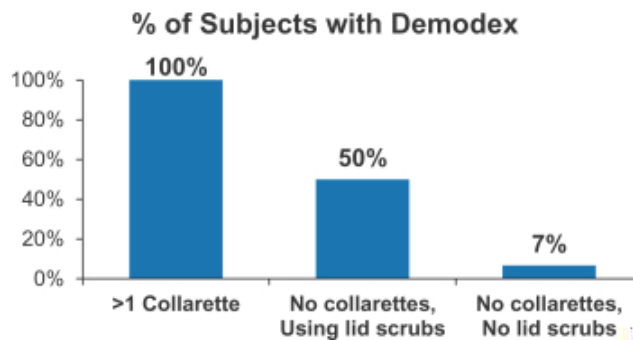
Figure 6: Collarettes Are the Pathognomonic Sign of Demodex Blepharitis



A clinical trial confirmed the pathognomonic relationship of the collarette to Demodex infestation. As illustrated in the figure below, 100% of patients with at least one collarette had Demodex infestation, while only 7% of patients without collarettes had Demodex. Even for those subjects without collarettes, but who were performing daily lid scrubs with shampoo for a full year, 50% had Demodex infestation, implying that hygiene alone did not eradicate the mites.

The following figure shows that 100% of patients with at least one collarette had Demodex infestation:

Figure 7: 100% of Patients With at Least One Collarette Had Demodex Infestation



Demodex blepharitis can be easily diagnosed by ECPs with the standard eye examination, the 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.

Market Opportunity in Blepharitis

According to published studies, there are an estimated 20 million patients in the United States who suffer from blepharitis, with approximately 45%, or approximately 9 million, of cases caused by Demodex

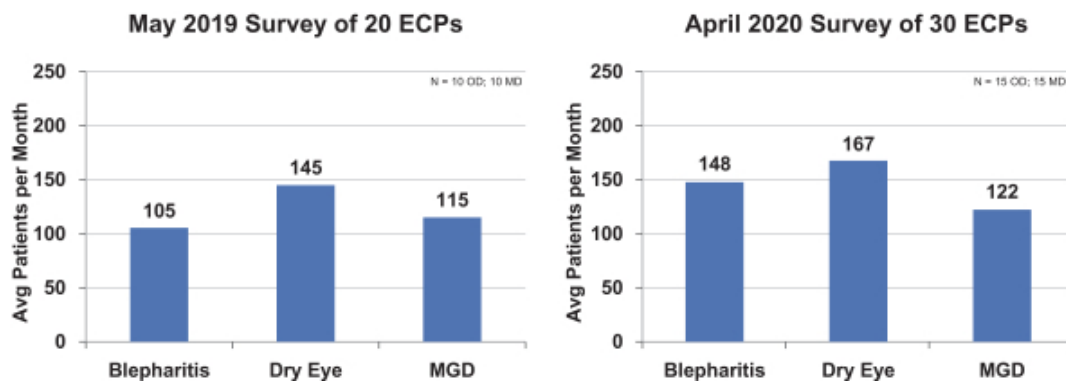
infestation. Further, our internal studies indicate the possibility that the number of Demodex blepharitis cases may be as high as approximately 25 million based on observation of collarettes in patients presenting to eye care clinics. Despite the high prevalence of patients with Demodex blepharitis and growing awareness of the condition amongst ECPs, there are no FDA-approved therapeutics for the treatment of blepharitis or for Demodex blepharitis. Although we believe blepharitis and Demodex blepharitis are significantly underdiagnosed conditions, with limited treatment alternatives, there are already an estimated 2.1 million annual blepharitis diagnoses in the United States.

Our Market Research Studies and Surveys

Our market research studies include an ECP survey of 50 ECPs conducted in 2019 and 2020 to determine ECP awareness of the connection between collarettes and Demodex infestation, or the ECP Survey. Twenty ECPs were interviewed in 2019 and 30 ECPs were interviewed in 2020. The ECP Survey showed that 44% of all diagnosed patients were over the age of 65, and 57% of diagnosed patients were female. Distribution of diagnoses across race and income metrics was approximately proportional to that of the United States population, implying little correlation of the condition with socioeconomic status. The ECP Survey also showed that in April through May of 2020, the number of blepharitis patients in the eye care clinic, which represented 60% of the total patients, was approaching the level of dry eye patients, which represented approximately 65% of the total patients. As the population of the United States continues to age, we believe this disease will become more prevalent.

The following figures show that according to the ECP Survey, the number of blepharitis diagnoses approached the number of dry eye diagnoses. This trend is also supported by independent epidemiology studies:

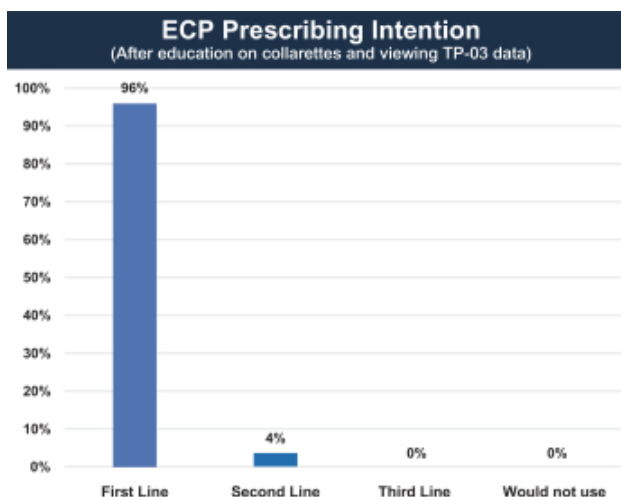
Figures 8 and 9: Blepharitis Diagnoses Approaching Number of Dry Eye Diagnoses



We have sponsored two additional market research studies to attain ECP feedback on the TP-03 product profile. In these studies, a total of 25 ophthalmologists and 25 optometrists were educated on the pathognomonic relationship of collarettes to Demodex blepharitis and exposed to the Mars and Jupiter clinical trial data. After exposure, ECPs were asked whether they would prescribe TP-03 for their patients presenting with Demodex blepharitis as indicated by collarettes. In these studies, 48 of 50 (96%) ECPs indicated that they would prescribe TP-03 as first-line treatment, and 2 of 50 (4%) indicated that they would prescribe it as second-line treatment. No ECPs indicated that they would prescribe TP-03 as third line or not prescribe TP-03.

The following figure shows that 96% of the surveyed ECPs indicated they would prescribe TP-03 as a first-line treatment:

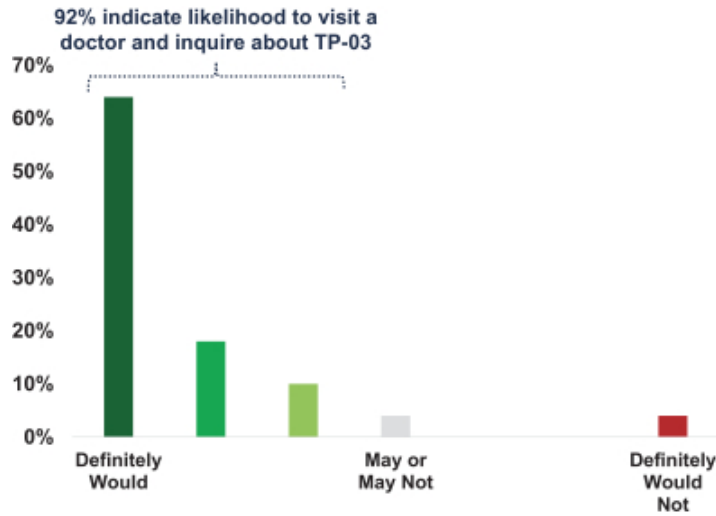
Figure 10: 96% of Surveyed ECPs Indicated Prescribing TP-03 as First-Line Treatment



We also sponsored a market research survey of 50 individuals with blepharitis symptoms, where the presence of “eye crust” on eye lashes was noted as a primary symptom. The individuals with blepharitis symptoms were educated on collarettes and that Demodex mites cause collarettes, and provided with a description of a hypothetical product with the target profile of TP-03, which can potentially eradicate Demodex mites in the eyelid and eliminate collarettes in a majority of patients. After considering the target product profile, the individuals with blepharitis symptoms were asked how likely they were to visit a doctor and ask about whether a product such as TP-03 would be right for them (on a scale of 1-7). Forty-six of 50 (92%) of the individuals with blepharitis symptoms indicated a likelihood to visit a doctor and ask about a product with a target profile of TP-03, and 32 of 50 (64%) indicated a response of “definitely would.” Two of 50 (4%) of the individuals with blepharitis symptoms indicated that they “may or may not,” and two of 50 (4%) of the individuals with blepharitis symptoms indicated that they “definitely would not.”

The following figure shows the results of this survey:

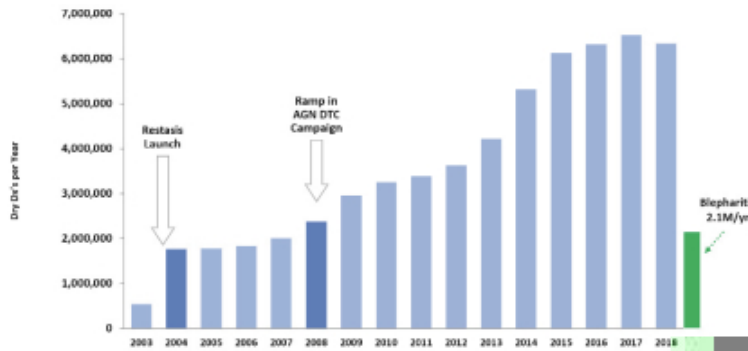
Figure 11: 92% of Individuals with Blepharitis Symptoms Indicated Likelihood To Inquire About a TP-03-Type Product



We believe that blepharitis is underdiagnosed due to the lack of an approved treatment and associated patient and physician education, and the lack of awareness of the role of Demodex mites in the disease process. The ECP Survey showed that only 10-15% of ECPs were aware that collarettes are highly correlated with Demodex infestation. Despite the current lack of awareness by ECPs, we believe that the ocular surface disease marketplace is highly responsive to education of both the ECP and the patient. For example, as a result of ECP and patient education the dry eye market grew significantly once there was a product to address the large, latent demand for an effective therapy. Dry eye had no approved therapeutic until 2003. With the approval of Allergan’s Restasis (cyclosporine) in 2003 and concurrent ECP and patient education, the diagnosis rate increased by approximately 12x, growing from 500,000 diagnoses in 2003 to over 6 million annual diagnoses by 2015. Annual diagnoses rates have been maintained at similar levels since 2015 and, in 2016, Restasis generated peak revenue \$1.5 billion.

The following figure shows the annual diagnoses of dry eye disease prior to and after and the launch of Restasis, with the 2.1 million diagnoses for blepharitis in 2019 shown on the plot for reference:

Figure 12: Dry Eye Diagnoses Per Year



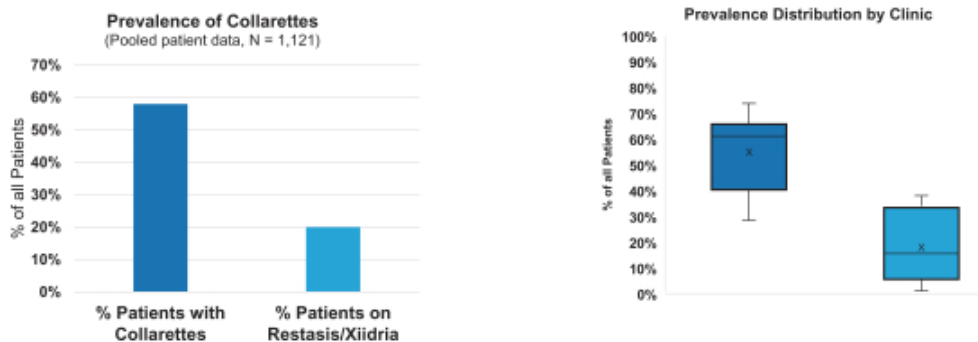
[Table of Contents](#)

Demodex mites have been implicated in approximately 45% of all blepharitis cases in a meta-analysis of 11 studies consisting of an aggregate of 4,741 patients with blepharitis. The incidence of Demodex blepharitis increases progressively with aging, which is the main risk factor for the condition, with the majority of people over the age of 60 having been shown to have the disease.

Our market research studies also included an epidemiological evaluation of 1,121 consecutive patients in eight ophthalmology and optometry practices conducted in 2020, or the Patient Survey, which showed that 58% of all patients entering the practices had collarettes. By comparison, 20% of those same 1,121 patients were currently on a prescription therapeutic for dry eye disease (Restasis or Xiidra). The clinics in the Patient Survey were geographically diverse and represented both high and low dry eye prescription rates. Each practice was required to enroll between 100 and 180 consecutive patients. The clinic with the lowest prevalence demonstrated 29% of consecutive patients had collarettes, and the clinic with the highest prevalence demonstrated 76% of consecutive patients had collarettes.

The following figure shows the prevalence of collarettes and prevalence distribution by clinic, from the Patient Survey:

Figures 13 and 14: Prevalence of Collarettes



We believe the data has demonstrated that there is a significant population for blepharitis, and for Demodex blepharitis more specifically. We also believe the data illustrates a significant opportunity to increase the diagnosis rate of Demodex blepharitis by educating ECPs on the high correlation of the presence of collarette to Demodex blepharitis in order for ECPs to incorporate the examination of the condition into standard practice.

Over the past several years, an increasing number of clinical studies on Demodex have been published in the context of ocular surface disease, with more than half of these studies published in the last four years. We believe this shows an increased understanding of the importance of Demodex in the scientific ophthalmology community and represents an important step in educating ECPs about Demodex blepharitis.

Current Treatment Options and Their Limitations

Despite the high prevalence of patients with Demodex blepharitis and growing awareness of the condition amongst ECPs, there are no FDA- approved therapeutics for the treatment of blepharitis or for Demodex blepharitis. 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;

[Table of Contents](#)

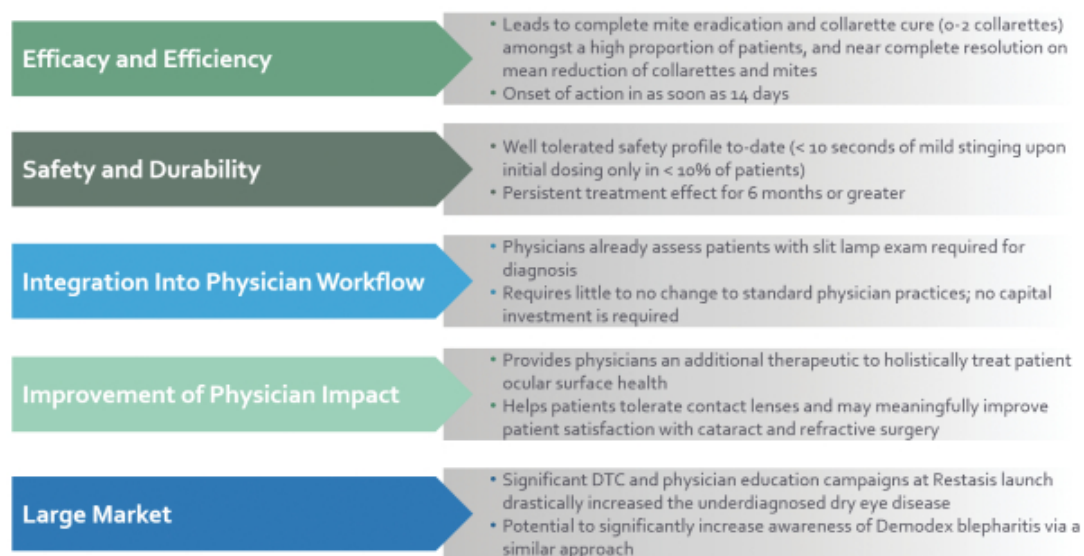
- insufficient definitive knowledge of diagnostic criteria to guide treatment decisions;
- prohibitive side effects (significant burning and stinging) from treatments that target Demodex mites (e.g. tea tree oil); and
- current treatments do not eradicate the Demodex mites, leading to a chronic and progressive condition.

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 first-in-class therapeutic based on the novel 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 applicable primary and secondary endpoints in 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.

The following figure summarizes the key advantages of TP-03:

Figure 15: Summary of TP-03 Key Advantages



Commercial Strategy for Demodex Blepharitis Launch

If approved, we plan to commercialize TP-03 in the United States with a focused, specialty sales force, direct-to-consumer, or DTC, campaign, and ECP education campaigns with KOLs and professional associations. In our work with KOLs and various associations to increase Demodex blepharitis awareness and education, we plan to highlight prevalence, impact, and simplicity of diagnosis of Demodex blepharitis. Our goal is to educate ECPs about the prevalence of Demodex blepharitis and the safety and efficacy 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.

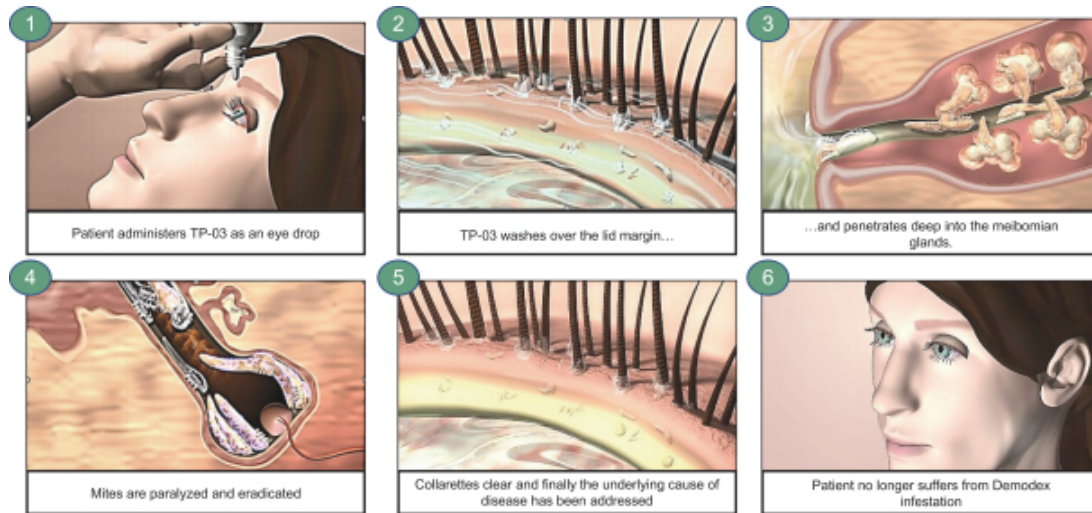
TP-03 Eye Drops – Mechanism of Action

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 a low affinity to mammalian GABA-Cl and other ion channels (e.g. hERG) and thus has no 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 show the intended paralysis of mites in the hair follicle by TP-03 administration:

Figure 16: Progression of TP-03 Application, Mite Paralysis and Eradication



Clinical Development Program

We have completed four Phase 2 clinical trials to date, along with one additional *ex vivo* study. The table below summarizes completed and planned clinical investigations evaluating TP-03 for Demodex blepharitis. We plan to evaluate TP-03 in two Phase 3 pivotal registration trials, referred to as Saturn-1 and Saturn-2. Saturn-1 is a Phase 3, randomized, controlled, double-blind trial to evaluate the safety and efficacy of TP-03 in approximately 350 Demodex blepharitis patients in multiple centers in the United States. Saturn-1 is expected to begin enrollment in 2020 and top-line data is expected in 2021, subject to the impact of the ongoing COVID-19 pandemic. Saturn-2, our confirmatory Phase 3 randomized, controlled, double-blind trial, has a highly comparable design to that of Saturn-1 and is also expected to enroll approximately 350 Demodex blepharitis patients. Enrollment of Saturn-2 is expected to begin in 2021, subject to the impact of the ongoing COVID-19 pandemic. We expect these trial results to support the potential submission of an NDA for TP-03 for the treatment of Demodex blepharitis.

The following figure shows our completed and planned investigations evaluating TP-03 for Demodex blepharitis:

Figure 17: Completed and Planned Investigations Evaluating TP-03 for Demodex Blepharitis

Trial / Study	Design	Objectives	Results	Status	
PoC: Mercury	Ex-vivo mite testing on 80 mites	Ex-vivo mite death count	100% mites dead within 24 hours (p < 0.001)		
Clinical Trials			Collarette Cure Rate***	Mite Eradication Rate	
P2a: Mars *	28-day BID dosing, single arm (n=15) Pilot formulation	Collarette grade Mite density Safety	86% at 28 days (p < 0.05)	57% at 28 days (p < 0.05)	
P2b: Jupiter *	28-day BID dosing, randomized 1:1 (n=60) Pilot formulation	1 ^o – Collarette grade 2 ^o – Mite density Safety	88% at 28 days (p < 0.001)	67% at 28 days (p < 0.005)	
P2a: Io	42-day BID dosing, single arm (n=18) Current formulation	1 ^o – Collarette cure 2 ^o – Mite eradication Safety	72% at 42 days (p < 0.05)	78% at 42 days (p < 0.05)	
P2b: Europa	42-day BID dosing, randomized 1:1 (n=54) Current formulation	1 ^o – Collarette cure 2 ^o – Mite eradication 2 ^o – Redness Composite Safety	80% at 42 days (p < 0.001)	73% at 42 days (p = 0.003)	
P3: Saturn-1	42-day BID dosing, randomized 1:1 (n=350) Current formulation **	1 ^o – Collarette cure 2 ^o – Mite eradication 2 ^o – Redness Composite Safety	Initiate trial in 2020		
P3: Saturn-2	42-day BID dosing, randomized 1:1 (n=350) Current formulation **	1 ^o – Collarette cure 2 ^o – Mite eradication 2 ^o – Redness Composite Safety	Initiate trial in 2021		

* The Mars and Jupiter trials used collarette grade as an endpoint, which has been translated into a collarette cure (refined as <10 collarettes). This is different from the collarette cure (defined as <2 collarettes) endpoint used in Io, Europa and the planned Saturn-1/2 trials. Mite density is translated into mite eradication, which is defined as 0 mites consistently throughout trial.

** Expected design pending FDA feedback.

*** Primary endpoint in Io, Europa, and intended in Saturn-1 and Saturn-2, is cure based on collarette grade.

Represents pivotal trial Same endpoints and formulation of TP-03 as Saturn trials

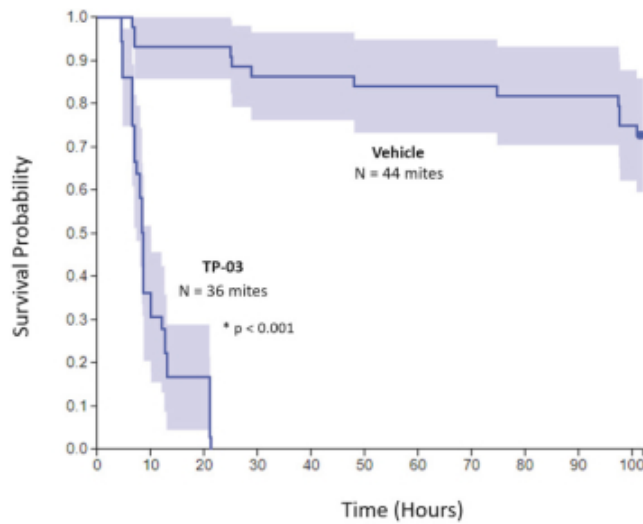
TP-03 is a presentation of lotilaner, the API, formulated into a topical eye drop formulation. Only one dose strength of TP-03, 0.25% lotilaner solution was used across all clinical trials and studies.

Mercury Study

The Mercury preclinical study was an *ex vivo* study of the efficacy of TP-03 in causing the paralysis and death of Demodex mites performed at a single center in the United States in 2019 through 2020. Mites were collected following lash plucking at a single center in the United States. Mites were placed in small wells and submersed in a drop of either TP-03 (pilot formulation) or a vehicle control (formulation with no active ingredient). The *ex vivo* efficacy results of the Mercury study show that 100% of mites subjected to the pilot formulation of TP-03 were dead within 24 hours and more than 70% of mites subjected to the formulation with no active ingredient were still viable after four days of observation.

The following figure presents the efficacy results on Demodex mite survival probability over time, with the shaded regions representing the 95% confidence interval for each of the two groups:

Figure 18: Mercury Study *Ex Vivo* Efficacy Results



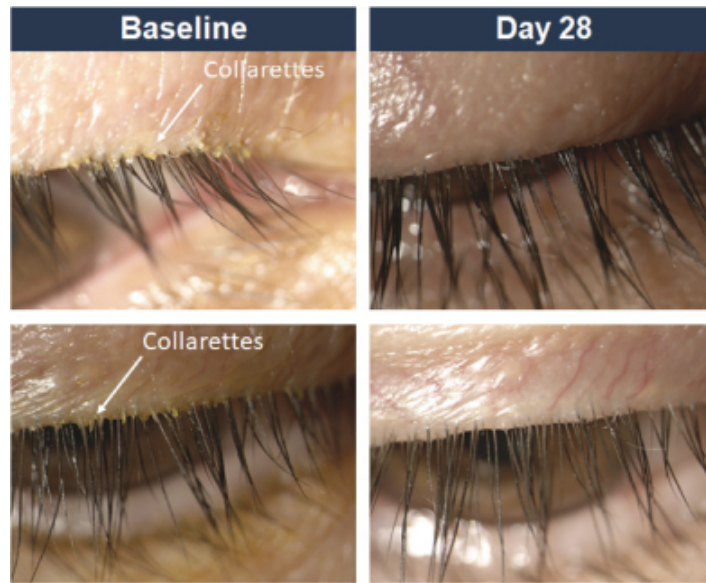
Mars Phase 2a Single-Arm Clinical Trial

Mars was a Phase 2a single-arm clinical trial which evaluated the safety and efficacy of TP-03 for the treatment of Demodex blepharitis completed in 2019 in Mexico City, Mexico at a well-established site for ocular therapy trials. Subjects were treated with TP-03 (pilot formulation) BID for 28 days and followed to 90 days (62 days post-treatment). A total of 18 subjects were enrolled in the trial, with 15 patients receiving treatment. All 15 subjects who received treatment completed the trial through day 28. Twelve of the 15 subjects continued through 90 days (62 days post-treatment) and three subjects did not continue the trial after day 28.

Exploratory endpoints included collarette grading score and mite density, as assessed by microscopic evaluation of plucked lashes. As this was an exploratory Phase 2a trial, no primary or secondary endpoints were pre-specified. We utilized the data from the exploratory endpoints to determine collarette cure and mite eradication rates. We defined collarette cure as collarette count of 10 or fewer, consistent with prior studies in the field. We defined mite eradication as zero mites per lash.

The following figure illustrates representative photos of two Mars subjects at baseline and day 28 who exhibited a collarette cure:

Figure 19: Two Mars Trial Subjects at Baseline and Day 28 Who Exhibited a Collarette Cure

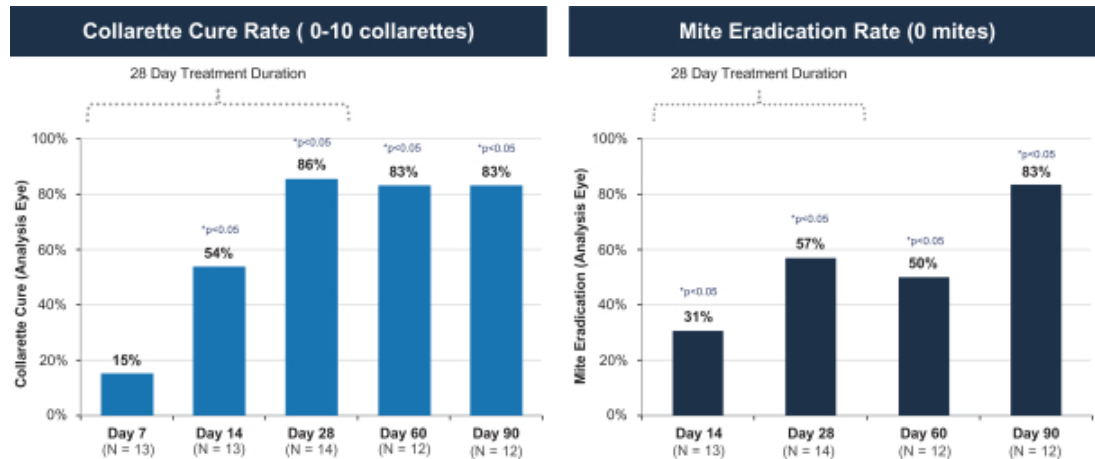


The proportion of subjects who exhibited a collarette cure was statistically significant compared to baseline by day 14 with 54% of subjects (7 of 13 subjects, $p < 0.05$) exhibiting a cure, at day 28 with 86% of subjects (12 of 14 subjects, $p < 0.05$) exhibiting a cure, and post-treatment at day 60 with 83% of subjects (10 of 12 subjects, $p < 0.05$) exhibiting a cure and at day 90 with 83% of subjects (10 of 12 subjects, $p < 0.05$) exhibiting a cure.

The proportion of subjects who exhibited mite eradication was statistically significant compared to baseline at day 14 with 31% of subjects (4 of 13 subjects, $p < 0.05$) exhibiting eradication, at day 28 with 57% of subjects (8 of 14 subjects, $p < 0.05$) exhibiting eradication, and post-treatment at day 60 with 50% of subjects (6 of 12 subjects, $p < 0.05$) exhibiting eradication and day 90 with 83% of subjects (10 of 12 subjects, $p < 0.05$) exhibiting eradication.

The following figure shows the data for each visit day:

Figures 20 and 21: Mars Phase 2a Trial Collarette Cure and Mite Eradication Rates



There were no adverse events reported and TP-03 was well tolerated. No subjects discontinued the trial due to adverse events.

Jupiter Phase 2b Trial

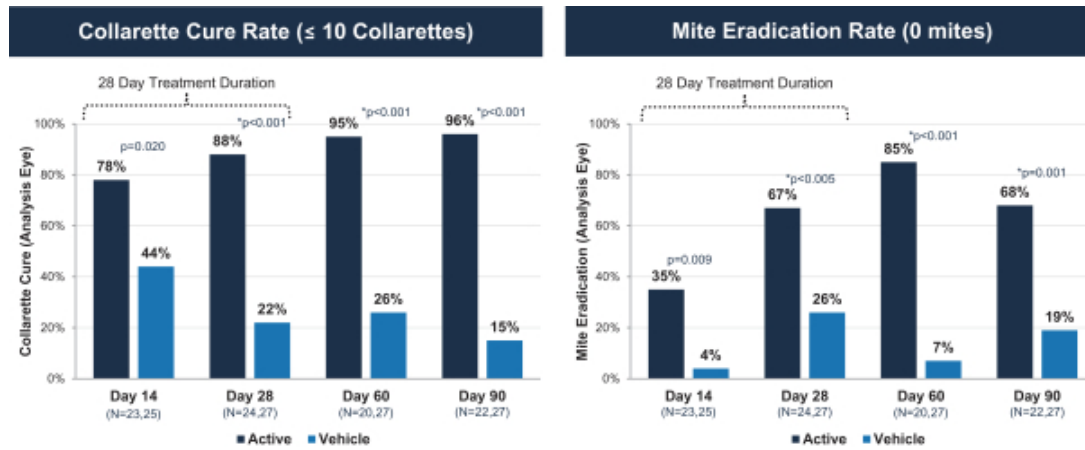
Jupiter was a Phase 2b randomized, controlled, double-blind trial which evaluated the safety and efficacy of TP-03 for the treatment of Demodex blepharitis completed in 2019 in Mexico City, Mexico at a well-established site for ocular therapy trials. Subjects were treated with either TP-03 or with a vehicle control BID for 28 days. Subjects were followed to 90 days (62 days post-treatment) to evaluate post-treatment duration of effect. The primary endpoint was mite density for the treatment group as compared to the mite density for the vehicle control group at day 28. We utilized the collarette grading and mite density data to determine collarette cure and mite eradication rates. The definitions of collarette cure and mite eradication in the Jupiter trial were consistent with those used in the Mars trial. A total of 60 subjects were enrolled in the trial, with 51 subjects receiving treatment through day 28 and 49 subjects completing the trial through day 90.

The proportion of subjects who exhibited a collarette cure was statistically significant for the pilot formulation TP-03 compared to vehicle control at day 14 (78% vs 44% subjects, $p = 0.020$), day 28 (88% vs. 22%, $p < 0.001$) and post-treatment at day 60 (95% vs 26%, $p < 0.001$) and day 90 (96% vs. 15%, $p < 0.001$).

The proportion of subjects who exhibited mite eradication was statistically significant for the pilot formulation of TP-03 compared to vehicle control at day 14 (35% vs 4% subjects, $p = 0.009$), day 28 (67% vs. 26%, $p = 0.005$) and post-treatment at day 60 (85% vs 7%, $p < 0.001$) and day 90 (68% vs. 19%, $p = 0.001$).

The following figures show the collarette cure and mite eradication rates for each visit day:

Figures 22 and 23: Jupiter Trial Collarette Cure and Mite Eradication Rates



There were no serious adverse events reported and TP-03 was well tolerated. Any adverse events were not related to treatment and no subjects discontinued the trial due to adverse events.

Trials With Updated Protocol and Formulation Designed to Support Pivotal Trials

Io Phase 2a Trial

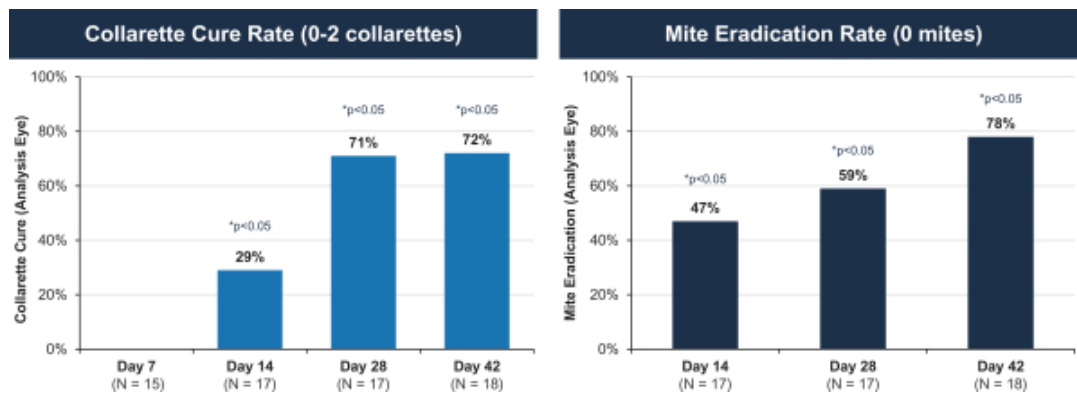
Io was a Phase 2a single-arm trial which evaluated the safety and efficacy of TP-03 for the treatment of Demodex blepharitis completed in 2020 in Mexico City, Mexico at a well-established site for ocular therapy trials. The design of the Io trial took into account feedback from the FDA, and accordingly we subsequently defined collarette cure rate to a more stringent definition of less than or equal to two collarettes on the eyelid. The definition of mite eradication, defined as zero mites per lash, remained consistent with that of the Mars and Jupiter trials. In the Io trial we also utilized for the first time in clinical trials the formulation of TP-03 which is expected to support our NDA submission for Demodex blepharitis. The Io trial design, as well as the formulation of TP-03 utilized, are consistent with the design and formulation to be utilized in our Saturn-1 Phase 3 trial. The primary efficacy endpoint was the proportion of patients experiencing a cure based on collarette grade, or collarette cure, at day 42. The secondary endpoint was the mite eradication rate at day 42. A total of 18 subjects were enrolled in the trial, all of whom were crossed over from the vehicle control group of the Jupiter trial.

The proportion of subjects who exhibited a collarette cure was statistically significant compared to baseline by day 14 with 29% of subjects (5 of 17 subjects, p < 0.05), at day 28 with 71% of subjects (12 of 17 subjects, p < 0.05) and at day 42 with 72% of subjects (13 of 18 subjects, p < 0.05).

The proportion of subjects who exhibited mite eradication was statistically significant compared to baseline by day 14 with 47% of subjects (8 of 17 subjects, p < 0.05), at day 28 with 59% of subjects (10 of 17 subjects, p < 0.05) and at day 42 with 78% of subjects (14 of 18 subjects, p < 0.05).

The following figures present the collarette cure and mite eradication rates for each visit day:

Figures 24 and 25: Io Trial Collarette Cure and Mite Eradication Rates



All 18 subjects completed the trial through day 42 of dosing. There were no serious adverse events reported and TP-03 was well tolerated. No subjects discontinued the trial due to adverse events. The most common adverse event included mild transient burning after administration for less than 10 seconds.

The following table provides a summary of treatment emergent adverse events for the trial:

Figure 26: Summary of Treatment Emergent Adverse Events

Adverse Event	N = 18 n (%)
Transient burning	4 (22%)
Transient blurriness	1 (6%)

Europa Phase 2b Trial

Europa was a Phase 2b randomized, controlled, double-blind trial, which evaluated the safety and efficacy of TP-03 for the treatment of Demodex blepharitis completed in 2020 in Mexico City, Mexico at a well-established site for ocular therapy trials. Like the Io trial, the Europa trial was designed with the same protocols and formulation as will be utilized in our Saturn-1 Phase 3 trial. Subjects were treated with either TP-03 or with a vehicle control BID for 42 days. A total of 54 subjects were enrolled in the trial with 34 subjects completing the trial through day 42.

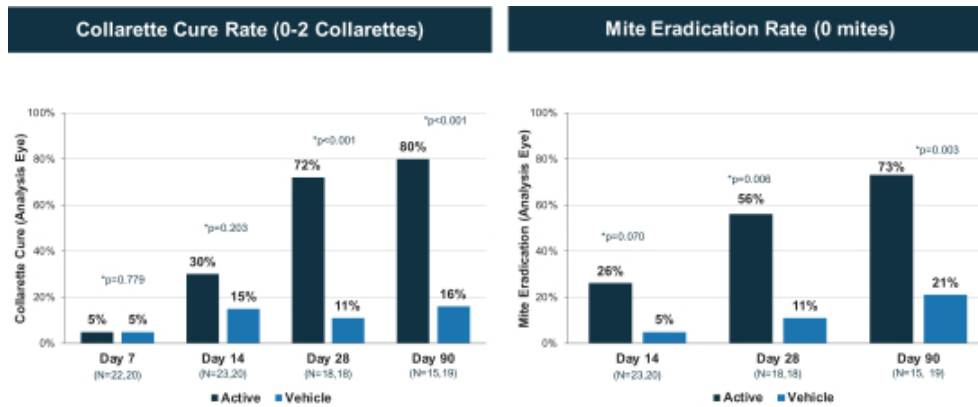
The primary efficacy endpoint was the proportion of patients experiencing a cure based on collarette grade of two or fewer collarettes on the eyelid, or collarette cure, as compared to the vehicle control, at day 42. Secondary efficacy endpoints included (1) mite eradication compared to vehicle control (defined as zero mites per lash) at day 42, and (2) a composite cure rate of collarette cure and zero lid erythema compared to vehicle control. Subjects were also asked to rate the comfort of the trial eye drop at day 42.

The proportion of subjects who exhibited a collarette cure was statistically significant for TP-03 compared to vehicle control at day 28 (72% vs 11% subjects, $p < 0.001$) and day 42 (80% vs. 16%, $p < 0.001$).

The proportion of subjects who exhibited a mite eradication was statistically significant for TP-03 compared to vehicle control at day 28 (56% vs 11% subjects, $p = 0.003$) and day 42 (71% vs. 21%, $p = 0.015$).

The following figures show the collarette cure and mite eradication rates for each visit day:

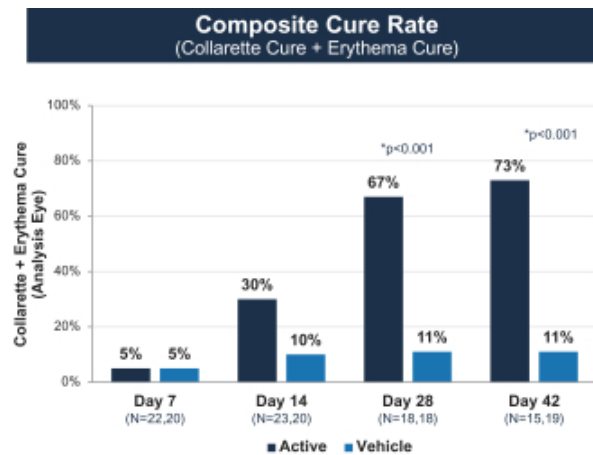
Figures 27 and 28: Europa Trial Collarette Cure and Mite Eradication Rates



The proportion of subjects who exhibited composite cure rate of collarette cure combined with zero lid erythema was statistically significant for TP-03 compared to vehicle control at day 28 (67% vs 11% subjects, $p < 0.001$) and day 42 (73% vs. 11%, $p < 0.001$).

The following figure shows data for each visit day:

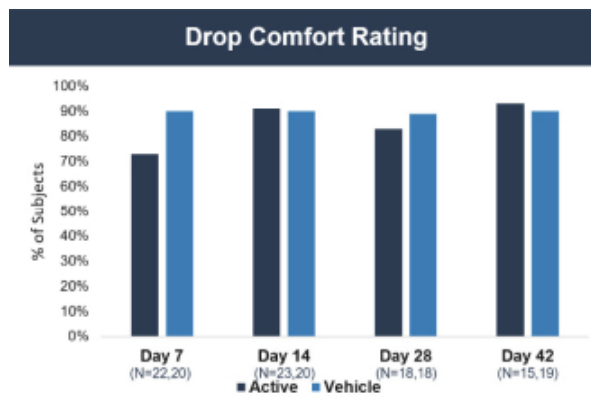
Figure 29: Composite Cure Rate was Statistically Significant for TP-03 Compared to Vehicle Control



The figure below shows how subjects rated drop comfort at each visit in each of the active and vehicle control groups. The bars shows the percentage of patients who rated the drop as either “very comfortable,” “slightly comfortable” or “neither comfortable or uncomfortable” in both the active and vehicle control groups for each visit day. There was only one subject, in the vehicle group, that rated the drop as “very uncomfortable” and only at days 14 and 28. All other subjects that did not rate the drop as “very comfortable”, “slightly comfortable” or “neither comfortable or uncomfortable” rated the drop as “slightly uncomfortable.” At day 7, the drop was rated as “slightly uncomfortable” by 6/22 (27.3%) in the active group, 2/20 (10.0%) in the vehicle control group and 8/42 (19.0%) overall.

The following figure shows the drop comfort ratings at each visit day:

Figure 30: Comfort Ratings



No subjects discontinued the trial due to an adverse event and TP-03 was well tolerated. All adverse events were mild in severity.

The following table provides a summary of treatment related or possibly related adverse events for the trial:

Figure 31: No Subjects Discontinued Europa Trial Due to Adverse Event

Adverse Event	Active N = 23 n (%)	Vehicle N = 20 n (%)
Transient burning	3 (13%)	1 (4%)
Transient eye redness	1 (4%)	—
Transient blurriness	1 (4%)	—

TP-03 Safety Profile From Phase 2 Clinical Trials

Our Phase 2 trial data indicates that TP-03 was well tolerated with no significant adverse events leading to treatment discontinuation across the four trials. A total of 82 subjects have received one or more doses of TP-03 and have had at least one follow-up visit; while 52 subjects received the vehicle control. Only nine subjects treated with TP-03 had treatment-related adverse events, versus one subject treated with the vehicle control. The most common treatment-related adverse events, or TRAEs, reported were burning after administration, which was reported in seven subjects (8.5%) receiving TP-03 versus one subject (1.9%) receiving the vehicle control. Other TRAEs reported for subjects treated with TP-03 were blurred vision in two subjects (2.4%), dysgeusia in one subject (1.2%), and instillation site erythema in one subject (1.2%); with no corresponding TRAEs reported in subjects treated with vehicle.

Adverse events deemed unrelated to treatment occurred in five subjects treated with TP-03, with diarrhea reported in two subjects (2.4%), hypertension reported in one subject (1.2%), cataract operation reported in one subject (1.2%), and pharyngotonsillitis reported in one subject (1.2%).

For subjects treated with the vehicle control, the six subjects reported adverse events unrelated to treatment, which consisted of diarrhea in three subjects (5.7%) and viral upper respiratory tract infection in three subjects (5.7%).

[Table of Contents](#)

Furthermore, there was little or no change in mean corrected distance visual acuity across all four trials, and only one subject treated with TP-03 showed a worsening of 0.22 logMAR from baseline to day 28 in the left eye. This subject did not return for their follow-up visit on day 42. Intraocular pressure was recorded in the Mars, Jupiter and Europa trials, and there were only minor reported changes observed in both the active and the vehicle control. The most common clinically significant slit lamp examination finding was an increase from baseline in corneal staining. The increases in staining were typically transient, occurring at only a single visit, and, in the controlled trials, occurred more often in subjects treated with the vehicle control versus subjects treated with TP-03. The only other slit lamp examination finding was conjunctival hyperemia in one subject receiving TP-03 at day seven and one subject receiving the vehicle control at day 14.

Disease Recurrence Following End of Treatment Course

Subjects from the Mars and active arm of the Jupiter trials were followed for one year after enrollment. Combined interim data for recurrence of clinical grade Demodex blepharitis, defined as a collarette score of two or more, and mite density of one or more per lash. The data show a persistent treatment effect of TP-03 for six months or greater for collarette score, with meaningful recurrence of collarettes occurring after six months with the recurrence increasing considerably one year after treatment. Mites recurred more quickly than collarettes, consistent with collarettes being composed of mite byproducts. Subsequent to initial treatment, we believe that TP-03 may be utilized by patients and ECPs for intermittent re-treatment based on the disease recurrence observed.

Planned Pivotal Trials

Saturn-1 and Saturn-2 Trials

Saturn-1 is a randomized, controlled, double-blind trial that we plan to initiate in 2020 to evaluate the safety and efficacy of TP-03 for the treatment of Demodex blepharitis in multiple centers in the United States. Target enrollment for the trial is approximately 350 subjects, enrolled 1:1 between a BID dose of TP-03 and a vehicle control. Saturn-1 is designed for subjects to receive treatment for 42 days and be subsequently followed for safety under a separate protocol for one year. The primary efficacy endpoint is proportion of subjects with cure based on a collarette grade of zero (± 2) at day 43. The two secondary endpoints are (1) proportion of subjects with Demodex eradication (0 mites/lash) at day 43 and (2) proportion of subjects with a composite of collarette and erythema cure at day 43 (collarette grade of zero combined with erythema score of zero). We expect enrollment of Saturn-1 to begin in 2020 and top-line data is anticipated in 2021, subject to the impact of the ongoing COVID-19 pandemic.

Saturn-2 is designed to be a confirmatory Phase 3 trial that we plan to initiate promptly after completing enrollment in Saturn-1. It is a randomized, controlled, double-blind trial to evaluate the safety and efficacy of TP-03 for the treatment of Demodex blepharitis in multiple centers in the United States. Target enrollment for the trial is approximately 350 subjects, enrolled 1:1 between a BID dose TP-03 arm and a vehicle control. Saturn-2 is designed for subjects to be followed for 43 days and receive treatment for 42 days. The primary efficacy endpoint is proportion of subjects with cure based on a collarette grade of zero at day 43. The two secondary endpoints are (1) proportion of subjects with Demodex eradication (0 mites/lash) at day 43 and (2) proportion of subjects with a composite of collarette and erythema cure at day 43 (collarette grade of zero combined with erythema score of zero). Enrollment of Saturn-2 is expected to begin in 2021, subject to the impact of the ongoing COVID-19 pandemic.

The protocol, including the subject inclusion and exclusion criteria and endpoints, and formulation are designed to be consistent with those of our Io and Europa Phase 2 trials. We expect that the data from the Saturn-1 and Saturn-2 trials will support our NDA filing for TP-03 in Demodex blepharitis.

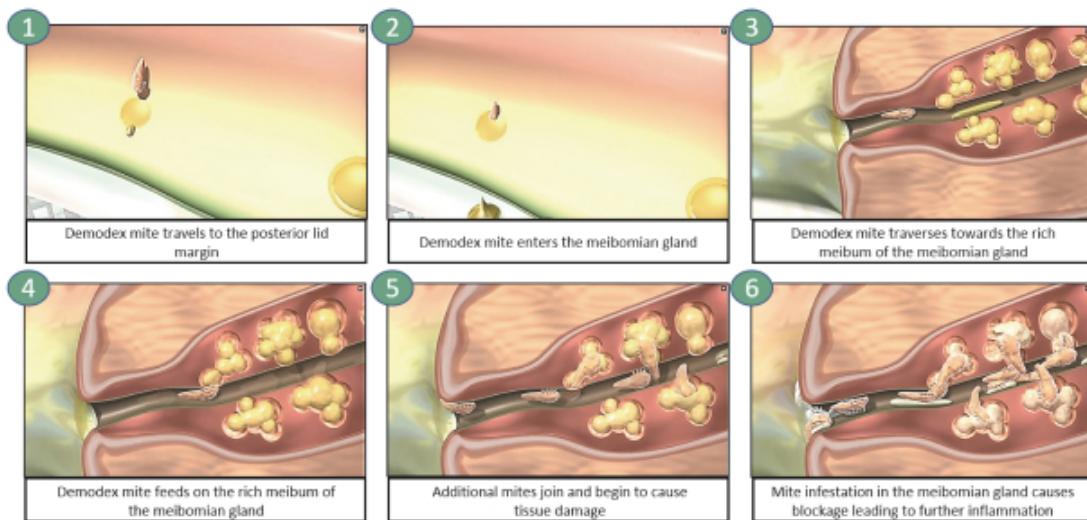
Development of TP-03 for Meibomian Gland Disease

Beyond Demodex blepharitis, we intend to explore the clinical potential for TP-03 in MGD, a chronic abnormality of the meibomian glands. MGD is commonly characterized in part by a widespread clogging of the meibomian glands that can result in tear film deficiency, and is one of the leading causes of dry eye disease. In the United States, MGD prevalence has been found to be approximately two-thirds of that 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 associated with MGD by virtue of causing the death of the *Demodex brevis* mites.

There are no FDA-approved therapeutics for MGD. MGD 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 and unmet need for an effective prescription therapeutic in MGD.

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

Figure 32: 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 United States are affected by rosacea and a study we conducted 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, or PPR, and patients who do not (non-PPR), with approximately 56% of patients presenting with the PPR phenotype and 44% presenting with the non-PPR phenotype, of treated patients whom are on topicals according to primary research we conducted of dermatologists. In addition, rosacea can be further divided into four subtypes.

[Table of Contents](#)

The cause of rosacea remains unclear 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* bacterium, also carried by Demodex mites, may play a role in the disease as well. In fact, Soolantra, the current standard of care for rosacea, has an anti-parasitic and Demodex targeting mechanism, suggesting that the clearance of Demodex plays a role in resolving the signs of symptoms of rosacea.

Current Treatment Options and Their Limitations

Rosacea is currently treated through topical anti-parasitic creams like ivermectin and azelaic acid, other topicals including PDE4 and JAK inhibitors, antibiotics like metronidazole, as well as other mechanisms such as alpha agonists. The current standard of care, Soolantra, is a branded anti-parasitic drug composed of 1% ivermectin cream, which targets Demodex mites but is only modestly effective, takes 8 to 12 weeks to show efficacy and is expensive at around approximately \$500 WAC for a 30-day supply.

Other treatments in development include Sol-Gel's Epsolay, a topical cream containing 5% encapsulated benzoyl peroxide, and Foamix's FMX103, a topical foam containing 1.5% minocycline, 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 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 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 proven 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 condition. We believe we can improve upon existing treatments in the market, like Soolantra, with an API that is more effective (longer half-life, more lipophilic, greater therapeutic window).

We are conducting *in vitro* studies and pharmacodynamics testing to identify a lead formulation of TP-04 we believe can compare favorably to Soolantra. We plan to evaluate whether TP-04 is safe and effective at treating the symptoms of PPR in a Phase 2a trial, which is expected to begin enrollment in 2021.

Chemistry, Manufacturing and Controls

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 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.

Table of Contents

The product candidate TP-03 is a presentation of lotilaner, the API, formulated into a topical eye drop formulation. Only one dose strength of TP-03 is currently being developed, 0.25% lotilaner solution. Since TP-03 is an anti-infective, only one strength, the maximum formulatable (0.25%), is required to be evaluated clinically.

We believe that our in-house supply of TP-03 is sufficient to complete Saturn-1, and that our in-house supply of cGMP lotilaner is sufficient to complete Saturn-2. 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 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, if possible, prior to submission of our NDA for TP-03. The drug product manufacturing is a compounding and aseptic filling operation that we believe could be transferred to additional CMOs as necessary.

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 United States. Current treatments for blepharitis in the United States 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,

Table of Contents

LLC, Eyevance Pharmaceuticals, Formosa Pharmaceuticals, Inc., Hovione Scientia, Nicox SA, Novaliq GmbH, Premark Pharma and Quorum Innovations. To our knowledge, Aperta Biosciences, LLC is the only company 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

In light of our stage of development, we have not yet established a commercial organization or distribution capabilities. If TP-03 receives marketing approval, we plan to commercialize TP-03 in the United States by developing our own sales organization targeting a subset of the approximately 25,000 prescribing ECPs in the United States. Throughout our commercialization efforts, we intend to educate ECPs on Demodex blepharitis and how to diagnose it with a simple slit lamp examination. Given the importance of increasing awareness and educating patients with blepharitis, we also anticipate deploying focused DTC marketing campaigns for TP-03. We expect to conduct most of the buildout of this organization following NDA submission and approval of TP-03, if obtained. Outside the United States, we intend to establish commercialization strategies for TP-03 as we approach possible commercial approval in each market, which may include collaborations with other companies.

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.

The term of individual patents varies depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the United States are effective for 20 years from the earliest effective filing date. In addition, in certain instances, a patent term can be extended to restore a portion of the term effectively lost as a result of the FDA regulatory review period. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date.

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, and/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

Table of Contents

or licensed to us worldwide include approximately 36 issued patents and approximately 23 pending patent applications. Certain of such patents and pending patent applications are related to lotilaner, and include treatment and composition of matter claims. We in-license patents and patent applications from Elanco issued or pending in, for example, the United States, Australia, Brazil, Canada, Chile, China, several European territories, India, Japan, Mexico, New Zealand, the Russian Federation, and Taiwan. The estimated natural expiration date of the issued in-licensed patents is approximately 2029 with a potential extension until 2032.

Approximately 16 of our owned pending patent applications relate to our TP-03 product, and include treatment and composition of matter claims (e.g., isoxazoline parasiticides for the treatment of *Demodex* blepharitis, and other conditions). These pending patent applications include applications in the United States, Australia, Brazil, Canada, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, the Russian Federation, South Africa, and the Patent Cooperation Treaty (PCT). If patents issue on our pending applications, the estimated natural expiration dates are between approximately 2038 and 2040.

While estimated expiration dates and descriptions of patents and patent applications are listed above, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, patent term adjustments, the availability of regulatory-related extensions, disclaimers, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

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 two U.S. pending trademark applications for the trademarks TARSUS and TARSUS PHARMACEUTICALS. In order to supplement the protection of our brand, we also own at least one registered internet domain name.

License Agreements

Elanco License Agreement

In January 2019, we entered into the Elanco Agreement 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. 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 Elanco Agreement. We utilize the intellectual property licensed under the 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 consent, additional third parties.

We made an upfront payment of \$1.0 million to Elanco at contract execution, which we recorded within “research and development” expense within our statements of operations for the year ended December 31, 2019. We will make further payments to Elanco upon our achievement of various clinical milestones up to an aggregate maximum of \$6.0 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.

[Table of Contents](#)

Either party may terminate the 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 Elanco Agreement, and fail to remedy such failure or cure such breach within 60 days, Elanco will have the right to terminate the Elanco Agreement. If we fail to meet any milestones by the achievement deadlines set forth in the 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 Elanco Agreement. If we fail to meet certain dermatological milestones by the achievement deadlines set forth in the 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 Elanco Agreement to the treatment, palliation, prevention or cure of eye diseases or conditions in humans only. If Elanco terminates the 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.

Under the terms of the Elanco Agreement, we grant to Elanco a 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 any use outside of our licensed field of use. We also grant Elanco a royalty-free, perpetual license to any intellectual property we conceive from our use of lotilaner, which license is exclusive in the field of animal health and non-exclusive for all other applications outside of our licensed field of use.

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.

Government Regulation

Government authorities in the United States 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 United States 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.

United States Drug Regulation

In the United States, we are subject to extensive regulation by the FDA, which regulates drugs under the Federal Food, Drug, and Cosmetic Act, or 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 United States. 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

Table of Contents

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 United States. 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, or GLP, requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin 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 GCD;
- 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 United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a 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

Table of Contents

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.

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 United States 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 United States.

Clinical trials in the United States 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

Table of Contents

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.

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.

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 United States.

Under the Prescription Drug User Fee Act, or 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 reviews 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. The FDA must make a decision on accepting an NDA for filing within 60 days of

[Table of Contents](#)

receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. 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.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an 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.

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 also may 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

Table of Contents

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 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 FDA 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

Table of Contents

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. Manufacturing, sales, promotion and other activities following product approval are subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments.

For example, in the United States, 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 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 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;

Table of Contents

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, 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 CMS information regarding direct or indirect payments and other transfers of value to physicians and teaching hospitals (and certain other practitioners beginning in 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 payors, 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, 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.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. CCPA creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA went into effect on January 1, 2020 and 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. 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.

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.

We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, as well as state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or

drug pricing. In addition, we may be subject to state and local laws that require the registration of pharmaceutical sales representatives.

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.

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

United States 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 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 United States 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, or 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 United States, 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 current regime, 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, or NCA, and one or more ethics committees. Under the current regime 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.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

European Union Drug Review and Approval

In order to market any product outside of the United States, 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.

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, in order to undertake a clinical trial in a European Union member state, an applicant must obtain approval from the competent national authority of the European Union member state in which the clinical trial is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. The EEA is comprised of the 27 Member States of the European Union and the three members of the EFTA pillar of the EEA, Iceland, Liechtenstein and Norway. Furthermore, the applicant may only start a clinical trial at a specific site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by an IMP dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, but it is not yet applicable in the European Union. The new legislation, which will be directly applicable in all European Union member states, aims to streamline the approval of clinical trials in the European Union by applying consistent rules and harmonizing the approvals process throughout the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point facilitating a harmonized assessment across multiple member states. The timing of implementation of the new Clinical Trials Regulation will be dependent on the development and launch of a fully functional clinical trials portal and database, which would be confirmed by an independent audit. The new legislation will come into effect six months after the European Commission publishes a confirmation of full functionality of the clinical trials information system. The website indicated that the audit was expected to commence in December 2020.

[Table of Contents](#)

Parties conducting certain clinical trials in the European Union must, as in the United States, post clinical trial information at the EudraCT website: <https://eudract.ema.europa.eu>.

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, or CHMP, of the EMA, and 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 Decentralised 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, or 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, SPC, 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 payors, such as government health programs, commercial insurance, and managed healthcare organizations. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are

Table of Contents

typically made by CMS or by Medicare's contractors and drug plans. These entities decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow their decisions regarding coverage and reimbursement to a substantial degree. However, 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 payor-by-payor basis.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors 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 to each payor separately, 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 B. Under the Medicaid Drug Rebate Program, we would be required to pay a 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 B. 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 VA 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, U.S. Department of Veterans Affairs, U.S. DoD, Public Health Service and U.S. Coast Guard, that is no higher than the statutory Federal Ceiling Price. 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

[Table of Contents](#)

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 United States 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. Effective April 1, 2022, Medicaid rebate liability will be expanded to include the territories of the United States as well.

There have been judicial challenges to certain aspects of the Affordable Care Act, as well as efforts by Congress to repeal or replace, and by the Trump administration to alter the implementation of, certain aspects of the Affordable Care Act. For example, on December 22, 2017, President Trump signed into law new federal tax legislation commonly referred to as the Tax Cuts and Jobs Act (the Tax Act) which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a federal district court in Texas ruled the individual mandate in the absence of the tax penalty is unconstitutional and, because it is a critical and inseparable feature of the Affordable Care Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the District Court's ruling, but remanded the case back to the District Court as to the question of severability. On March 2, 2020, the United States Supreme Court granted certiorari to review this case, which is expected to be decided in mid-2021. Additionally, the Further Consolidated Appropriations Act of 2020, Pub. L. No. 116-94, permanently eliminated, effective January 1, 2020, the Affordable Care Act-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and the medical device excise tax on non-exempt medical devices and, effective January 1, 2021, also eliminates the annual fee imposed on certain health insurance providers based on market share. 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 and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

Other legislative changes have been proposed and adopted in the United States 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, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional Congressional action is taken, with the exception of a temporary suspension of the 2% cut in Medicare payments from May 1, 2020 through December 31, 2020, pursuant to the CARES Act

[Table of Contents](#)

signed into law in March 2020 and designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several 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. For example, at the federal level, the Trump administration's budget for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. On July 24, 2020, President Trump signed several executive orders directed toward lowering drug prices. On October 9, 2019, HHS, OIG and CMS issued two proposed rules that set forth modifications to the Federal Anti-Kickback Statute, Civil Monetary Penalties Law and Physician Self-Referral Law (or the Stark Law) regulations to promote value-based and coordinated care arrangements. 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 payors often follow Medicare coverage policy and payment limitations in setting their own payment rates.

Employees

As of June 30, 2020, we had 12 employees, all of whom were full-time employees, and seven of whom were engaged in research and development activities. None of our employees are represented by a labor union or covered under a collective bargaining agreement.

[Table of Contents](#)

Facilities

We currently lease 10,879 square feet of office and laboratory space in Irvine, California under a lease that expires in February 2024. We believe that this space is sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms.

We also lease 3,290 square feet of office and laboratory space in Irvine, California under an existing lease that expires in April 2022. We plan to sublease this space.

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.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the names, ages and positions of our executive officers and directors as of June 30, 2020:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Executive Officers:		
Bobak Azamian, M.D., Ph.D.	42	President, Chief Executive Officer and Director
Leo M. Greenstein	44	Chief Financial Officer
Seshadri Neervannan, Ph.D.	52	Chief Operating Officer
Mark Holdbrook	67	Vice President, Clinical Affairs
Non-Employee Directors:		
Michael Ackermann, Ph.D.	38	Chairperson of the Board
Bhaskar Chaudhuri, Ph.D.	66	Director
Andrew Goldberg, M.D.	39	Director
Jason Tester	44	Director
William J. Link, Ph.D.	74	Director

Executive Officers

Bobak Azamian, M.D., Ph.D., is our co-founder and has served as our President since our inception, as our Chief Executive Officer since September 2018 and as a member of our board of directors since December 2016. From June 2012 to September 2018, Dr. Azamian co-founded and served as Chief Executive Officer, President, and Chief Medical Officer of Metavention, Inc., a company focused on treatment of diabetes and other metabolic diseases. Since September 2016, Dr. Azamian has also served as co-founder, co-Chairman and Chief Executive Officer of Vibrato Medical, Inc., a medical device company developing wearable treatments for peripheral arterial disease. Dr. Azamian previously served as an Entrepreneur in Residence at Versant Ventures from 2011 to 2013, and as a consultant and Senior Associate at Third Rock Ventures from 2007 to 2011, both venture capital firms focused on investing in early stage healthcare companies, and earlier served as a consultant at Amgen. He also completed residency in internal medicine and served as an attending hospitalist at Brigham and Women's Hospital from 2006 to 2011. Dr. Azamian received a B.A. in Biophysics from Rice University, a Doctor of Philosophy (Chemistry) from University of Oxford and a Doctor of Medicine from Harvard Medical School. We believe that Dr. Azamian is qualified to serve on our board of directors because of the perspective and experience he provides as our President and Chief Executive Officer as well as his broad experience within the life sciences industry.

Leo M. Greenstein has served as our Chief Financial Officer since April 2020. Mr. Greenstein previously served as Senior Vice President of Finance and Corporate Controller at Spectrum Pharmaceuticals, Inc. (Nasdaq: SPPI), a publicly-traded oncology pharmaceutical company from September 2013 until April 2020. Prior to Spectrum Pharmaceuticals, Mr. Greenstein served as Vice President of Finance and Corporate Controller at Endologix, Inc. (Nasdaq: ELGX), a publicly-traded medical device company, from May 2011 to September 2013, and Senior Director of Finance and SEC Reporting at Clariant, Inc., a then publicly-traded advanced oncology diagnostics services company, from June 2007 to April 2011, inclusive of his finance role with its then-majority shareholder. Mr. Greenstein spent eight years in Big-4 Public Accounting, beginning with Arthur Andersen LLP in September 1999 and ending with PriceWaterhouseCoopers LLP in June 2007. Mr. Greenstein received a B.A. in Accounting from Arcadia University and Juris Doctorate from the Temple University Beasley School of Law. He is an active attorney and member of the State Bar of California and is an active Certified Public Accountant in California.

Seshadri Neervannan, Ph.D. has served as our Chief Operating Officer since July 2020. Dr. Neervannan previously served as Senior Vice President of Global Pharmaceutical Development, from March

[Table of Contents](#)

2015 to July 2020 at Allergan Plc, and Vice President, Pharmaceutical Development, from January 2007 to February 2015 at Allergan Inc., a global pharmaceutical company. Prior to Allergan he was Director of Pharmaceuticals R&D, at Amgen Inc., a biotechnology company, from February 1999 to January 2007. From November 1994 to February 1999, Dr. Neervannan was Sr. Research Investigator at Bristol-Myers Squibb Pharmaceutical Research Institute. Dr. Neervannan received a B.S. in Pharmacy (with Honors) from Birla Institute of Technology & Science, Pilani, India, and a Ph.D. (with Honors) in Pharmaceutical Chemistry from the University of Kansas, Lawrence, KS.

Michael Holdbrook has served as our Vice President of Clinical Affairs since November 2018. Prior to this Mr. Holdbrook was an independent consultant from October 2017 to November 2018 and served as Senior/Executive Director for Oculeve/Allergan from May 2014 to October 2017. Mr. Holdbrook received a B.A. from the University of California at San Diego.

Non-Employee Directors

Michael Ackermann, Ph.D. has served as a member of our board of directors and as chairperson of our board of directors since July 2017. Dr. Ackermann has been the Chief Executive Officer of Presidio Medical, Inc. since September 2017 and chairman of the board of Oyster Point Pharma, Inc. (Nasdaq:OYST) since October 2017. Prior to that, he was Vice President, Neurostimulation for Allergan from August 2015 to June 2017 after serving as Chief Executive Officer of Oculeve, which was acquired by Allergan, from June 2012 to August 2015. Dr. Ackermann received a B.E. in biomedical engineering from Vanderbilt University and a M.S. and Ph.D. in biomedical engineering from Case Western Reserve University. We believe Dr. Ackermann is qualified to serve on our board of directors because of his substantial business and academic experience in the medical device and pharmaceutical development industries.

Bhaskar Chaudhuri, Ph.D. has served as a member of our board of directors since December 2019. Dr. Chaudhuri has more than 20 years' experience in pharmaceutical management, research and development. Since June 2011, he has been the Operating Partner at Frazier Healthcare Ventures. Prior to that time, Dr. Chaudhuri served as President of Valeant Pharmaceuticals International, Inc. from January 2009 to September 2010. Prior to joining Valeant, Dr. Chaudhuri served for seven years as President and Chief Executive Officer of Dow Pharmaceutical Sciences, Inc. and as a member of its board of directors from 2003 to 2008, at which time Dow was acquired by Valeant. Prior to that, Dr. Chaudhuri served as Executive Vice President of Scientific Affairs at Bertek Pharmaceuticals, Inc., a subsidiary of Mylan N.V., from 1998 to 2000. Prior to his positions at Bertek, Dr. Chaudhuri served as the General Manager of the Dermatology Division of Mylan. Dr. Chaudhuri joined Mylan through the acquisition of Penederm, Inc., where he worked from 1992 to 1998 in a number of senior positions before becoming the Vice President of Research and Development. Dr. Chaudhuri currently serves on the boards of directors of Arcutis Biotherapeutics, Inc., (Nasdaq: ARQT) since June 2016, Teligent Pharmaceuticals, Inc. (Nasdaq: TLGT) since November 2010 and Vyome Biosciences, Ltd. since June 2015. He also serves on the Advisory Board of the Berman Institute of John Hopkins University. Dr. Chaudhuri holds a Bachelor of Science degree in Pharmacy and an M.S. in Industrial Pharmacy from Jadavpur University and a Ph.D. in Pharmaceutics from the University of Louisiana. We believe Dr. Chaudhuri's qualifications to serve on the Board of Directors include his many years of experience in the pharmaceutical industry, including his prior positions in senior executive roles at major pharmaceutical companies.

Andrew Goldberg, M.D. has served as a member of our board of directors since August 2020. Since February 2016, Dr. Goldberg has served as a principal of Vivo Capital, a global healthcare investment firm that focuses exclusively on the life sciences industry. Prior to this, Dr. Goldberg was a consultant at McKinsey & Company from September 2014 to February 2016, where he served pharmaceutical, medical device, and biotechnology companies across a range of strategy, M&A, sales, marketing, and product development topics. Dr. Goldberg is a U.S. board-certified physician in both Critical Care Medicine and Emergency Medicine. He recently served as an Instructor in Medicine at the Mayo Clinic College of Medicine in Rochester, MN, from January 2013 to June 2013, where he also completed a fellowship in Critical Care Medicine and served as an

[Table of Contents](#)

Attending Physician in the Department of Emergency Medicine. Prior to this, he completed Emergency Medicine residency training at Los Angeles County + University of Southern California Medical Center (LAC+USC). His research has spanned a variety of topics, from traumatic brain injury and cardiac arrest to biomarker analysis and healthcare quality. He has over 25 scientific publications in leading peer-reviewed journals, including JAMA, Resuscitation, and the Cleveland Clinic Journal of Medicine. Dr. Goldberg received his M.D. from The George Washington University School of Medicine in Washington, DC, and a post-doctoral diploma in translational science from the Mayo Graduate School. He has held prior academic and clinical appointments at Oregon Health & Science University and the University of Arizona and currently at the Washington Township Medical Foundation. We believe Dr. Goldberg's qualifications to serve on the Board of Directors include his many years of experience in strategy and product development in the pharmaceutical industry, and his experience investing in pharmaceutical companies.

William J. Link, Ph.D. has served as a member of our board of directors since January 2017. Dr. Link is a managing director and co-founder of both Flying L Partners, a venture capital firm formed in 2016 to focus on investing primarily in the ophthalmic space, and Versant Venture Management LLC, a life science venture capital firm investing in early stage healthcare companies. Prior to co-founding Versant in 1999, Dr. Link was a general partner at Brentwood Venture Capital. From 1987 to 1997, Dr. Link was founder, chairman, and Chief Executive Officer of Chiron Vision Corporation (acquired by Bausch & Lomb). He also founded and served as President of American Medical Optics (acquired by Allergan). Dr. Link served as a director of Advanced Medical Optics (acquired by Abbott) from 2002 to 2009 and Inogen from 2003 to February 2014. Before entering the healthcare industry, Dr. Link was an assistant professor in the Department of Surgery at the Indiana University School of Medicine. He has been a member of the board of directors of Edwards Lifesciences Corporation (NYSE:EW) since May 2009, Second Sight Medical Products (Nasdaq:EYES) from 2003 to May 31, 2020, Glaukos Corporation (NYSE:GKOS) since 2001, and Oyster Point Pharma (Nasdaq: OYST) since July 2015. Dr. Link holds a B.S., an M.S., and a Ph.D. in mechanical engineering from Purdue University. We believe Dr. Link is qualified to serve on our board of directors because of his extensive experience in successfully commercializing products in the medical device industry, as well as his prior experience on the boards of U.S. public companies.

Jason Tester has served as a member of our board of directors since March 2018. Since September 2017 Mr. Tester has served as Chief Financial Officer of the Horowitz Group. From September 2008 to August 2017 Mr. Tester was Chief Financial Officer of AcuFocus, an ophthalmic medical device company. From July 2007 to May 2008, Mr. Tester was Vice President of Jefferies & Company, a healthcare investment bank. Mr. Tester holds an MBA in finance from the Emory University Goizueta Business School, a Master of Accountancy with a specialization in taxation and a Bachelor of Business Administration from the University of Georgia. We believe that Mr. Tester is qualified to serve on our board of directors because of his financial and accounting expertise and his experience in the life science industry.

Board Composition

Our board of directors is currently authorized to have six members and currently consists of six members, who were elected pursuant to the amended and restated voting agreement that we entered into with certain holders of our common stock and certain holders of our preferred stock and the related provisions of our amended and restated certificate of incorporation.

The provisions of this voting agreement will terminate upon the completion of this offering, after which there will be no further contractual obligations regarding the election of our directors. Our directors hold office until their successors have been elected and qualified or appointed, or the earlier of their death, resignation or removal.

In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering, our board of directors will be divided

Table of Contents

into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be held in 2021; , and and their terms will expire at the annual meeting of stockholders to be held in 2021;
- the Class II directors will be held in 2022; and , and and their terms will expire at the annual meeting of stockholders to be held in 2022; and
- the Class III directors will be held in 2023. , and and their terms will expire at the annual meeting of stockholders to be held in 2023.

Directors in a particular class will be elected for three-year terms at the annual meeting of stockholders in the year in which their terms expire. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Each director's term continues until the election and qualification of his or her successor, or the earlier of his or her death, resignation or removal.

Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering provide that only our board of directors can fill vacant directorships, including newly-created seats. Any additional directorships resulting from an increase in the authorized number of directors would be distributed pro rata among the three classes so that, as nearly as possible, each class would consist of one-third of the authorized number of directors.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See the section titled "Description of Capital Stock — Anti-Takeover Provisions — Certificate of Incorporation and Bylaw Provisions" elsewhere in this prospectus.

Director Independence

Upon the completion of this offering, we anticipate that our common stock will be listed on Nasdaq. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of this offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Exchange Act. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

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

To be considered independent for purposes of Rule 10C-1 and under the rules of Nasdaq, the board of directors must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of

Table of Contents

compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director and (ii) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that _____, representing _____ of our _____ directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the rules of Nasdaq, including in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled “Certain Relationships and Related Party Transactions” elsewhere in this prospectus. There are no family relationships among any of our directors or executive officers.

Board Leadership Structure

Our board of directors is currently chaired by Dr. Ackermann. As a general policy, our board of directors believes that separation of the positions of chairperson of our board of directors and Chief Executive Officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management’s performance and enhances the effectiveness of our board of directors as a whole. As such, Dr. Azamian serves as our President and Chief Executive Officer while Dr. Ackermann serves as the chairperson of our board of directors but is not an officer of the Company. We currently expect and intend the positions of chairperson of our board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure. Our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its oversight function directly as a whole. Our board of directors will also administer its oversight through various standing committees, which will be constituted prior to the completion of this offering, that address risks inherent in their respective areas of oversight. For example, our audit committee will be responsible for overseeing the management of risks associated with our financial reporting, accounting and auditing matters; our compensation committee will oversee the management of risks associated with our compensation policies and programs; and our nominating and corporate governance committee will oversee the management of risks associated with director independence, conflicts of interest, composition and organization of our board of directors and director succession planning.

Board Committees

Our board of directors will establish an audit committee, a compensation committee and a nominating and corporate governance committee prior to the completion of this offering. Our board of directors may

Table of Contents

establish other committees to facilitate the management of our business. Our board of directors and its committees will set schedules for meeting throughout the year and can also hold special meetings and act by written consent from time to time, as appropriate. Our board of directors expects to delegate various responsibilities and authority to committees as generally described below. The committees will regularly report on their activities and actions to the full board of directors. Each member of each committee of our board of directors will qualify as an independent director in accordance with the listing standards of Nasdaq. Each committee of our board of directors will have a written charter approved by our board of directors. Upon the completion of this offering, copies of each charter will be posted on our website at www.tarsusrx.com under the Investor Relations section. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. Members will serve on these committees until their resignation or until otherwise determined by our board of directors.

Audit Committee

The members of our audit committee are _____, _____ and _____, each of whom can read and understand fundamental financial statements. Each member of our audit committee is independent under the rules and regulations of the SEC and the listing standards of _____ applicable to audit committee members. _____ is the chair of the audit committee. Our board of directors has determined that each of _____ and _____ qualify as an audit committee financial expert within the meaning of SEC regulations and meet the financial sophistication requirements of Nasdaq.

Our audit committee will assist our board of directors with its oversight of the integrity of our financial statements; our compliance with legal and regulatory requirements; the qualifications, independence and performance of the independent registered public accounting firm; the design and implementation of our risk assessment and risk management. Among other things, our audit committee is responsible for reviewing and discussing with our management the adequacy and effectiveness of our disclosure controls and procedures. The audit committee also will discuss with our management and independent registered public accounting firm the annual audit plan and scope of audit activities, scope and timing of the annual audit of our financial statements, and the results of the audit, quarterly reviews of our financial statements and, as appropriate, initiates inquiries into certain aspects of our financial affairs. Our audit committee is responsible for establishing and overseeing procedures for the receipt, retention and treatment of any complaints regarding accounting, internal accounting controls or auditing matters, as well as for the confidential and anonymous submissions by our employees of concerns regarding questionable accounting or auditing matters. In addition, our audit committee has direct responsibility for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our audit committee has sole authority to approve the hiring and discharging of our independent registered public accounting firm, all audit engagement terms and fees and all permissible non-audit engagements with the independent auditor. Our audit committee will review and oversee all related person transactions in accordance with our policies and procedures.

Our audit committee operates under a written charter that satisfies the applicable rules of the SEC and the listing standards of Nasdaq. We believe that the composition of our audit committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

Compensation Committee

The members of our compensation committee are _____, _____ and _____ is the chair of the compensation committee. Each member of our compensation committee is independent under the rules and regulations of the SEC and the listing standards of Nasdaq applicable to compensation committee members. Our compensation committee will assist our board of directors with its oversight of the forms and amount of compensation for our executive officers (including officers reporting under Section 16 of the Exchange Act), the administration of our equity and non-equity incentive plans for employees and other service providers and certain other matters related to our compensation programs. Our compensation committee, among

Table of Contents

other responsibilities, evaluates the performance of our chief executive officer and, in consultation with him, evaluates the performance of our other executive officers (including officers reporting under Section 16 of the Exchange Act).

Our compensation committee operates under a written charter that satisfies the applicable rules of the SEC and the listing standards of Nasdaq. We believe that the composition of our compensation committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are _____, _____ and _____. Each member of our nominating and governance committee is independent under the rules and regulations of the SEC and the listing standards of Nasdaq, applicable to nominating and governance committee members. _____ is the chair of the nominating and corporate governance committee. Our nominating and corporate governance committee will assist our board of directors with its oversight of and identification of individuals qualified to become members of our board of directors, consistent with criteria approved by our board of directors, and selects, or recommends that our board of directors selects, director nominees; develops and recommends to our board of directors a set of corporate governance guidelines and oversees the evaluation of our board of directors.

Our nominating and corporate governance committee operates under a written charter that satisfies the applicable rules of the SEC and the listing standards of Nasdaq. We believe that the composition of our nominating and corporate governance committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

Compensation Committee Interlocks and Insider Participation

None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Conduct

Our board of directors will adopt a Code of Conduct, or the Conduct Code) prior to the completion of this offering. The Conduct Code will apply to all of our employees, officers, directors, contractors, consultants, suppliers and agents. Upon the completion of this offering, the full text of the Conduct Code will be posted on our website at www.tarsusrx.com under the Investor Relations section. We intend to disclose future amendments to, or waivers of, the Conduct Code, as and to the extent required by SEC regulations, at the same location on our website identified above or in public filings. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock. We have included our website address in this prospectus solely as an inactive textual reference.

Director Compensation

Prior to this offering, we have not implemented a formal policy with respect to compensation payable to our non-employee directors. Other than as set forth in the table and described more fully below, we did not pay any compensation, including equity awards, to any of our non-employee directors in 2019. We also reimburse our directors for expenses associated with attending meetings of our board of directors and its committees. Following the completion of this offering, we expect to implement an annual cash and equity compensation program for our non-employee directors.

[Table of Contents](#)

The following table presents the total compensation that we paid to Michael Ackermann, our only non-employee director who received compensation during the year ended December 31, 2019.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Option Awards (\$)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
Michael Ackermann	\$ 100,000	—	—	\$100,000

Directors who are also our employees or officers receive no additional compensation for their service as directors. See the section titled “Executive Compensation” elsewhere in this prospectus for additional information about the compensation of our employee directors.

EXECUTIVE COMPENSATION**Summary Compensation Table**

The following table shows information regarding the compensation of our named executive officers⁽¹⁾ for the fiscal year ended December 31, 2019.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)</u>	<u>Stock Awards (\$)</u>	<u>Option Awards (\$)</u>	<u>Non-Equity Incentive Plan Compensation \$(2)</u>	<u>Nonqualified Deferred Compensation Earnings \$(2)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
Bobak Azamian, MD, PhD <i>Chief Executive Officer</i>	2019	300,000	—	—	—	116,137	—	12,240	312,240
Mark Holdbrook <i>Vice President, Clinical Affairs</i>	2019	250,000	—	—	—	58,219	—	12,240	262,240

(1) Leo Greenstein and Sesha Neervannan were not executive officers prior to 2020 and, accordingly, compensation for prior years has not been included.

(2) Represents cash performance award earned with respect to prior fiscal year but paid in fiscal year 2020.

Narrative Explanation of Compensation Arrangements with our Named Executive Officers*Base Salaries and Annual Incentive Opportunities*

The base salaries of all of our named executive officers are reviewed from time to time and adjusted when our board of directors or compensation committee determines an adjustment is appropriate. For our 2019 fiscal year, the base salary was \$300,000 for Dr. Azamian and \$250,000 for Mr. Holdbrook.

Each of our named executive officers is eligible to earn an incentive bonus for each of our fiscal years, with such bonus awarded based on individual performance goals, as well as corporate goals related to our product development and advancement of clinical studies established by our chief executive officer and approved by our board of directors. During our fiscal year ended December 31, 2019, our named executive officers were eligible to earn cash incentive bonuses based on a combination of corporate and individual goals. We require that participants continue to be employed through the payment date to receive a bonus. For our 2019 fiscal year, the target bonus rate (as a percentage of base salary) was 30% for Dr. Azamian and 20% for Mr. Holdbrook.

Pursuant to his letter agreement with us, Dr. Azamian is eligible to receive certain acceleration benefits in the event of our change in control, as described in the footnotes to the “Outstanding Equity Awards at 2019 Fiscal Year-End” table.

Equity Compensation

We offer stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. Our stock options allow our employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant. In the past, our board of directors or compensation committee has determined the fair market value of our common stock based on inputs including valuation reports prepared by third party valuation firms. Generally, our stock options granted to new hires have vested as to 25% of the total number of option shares on the first anniversary of the award and in equal monthly installments over the following 36 months.

Table of Contents

Employee Benefits and Perquisites.

Our named executive officers are eligible to participate in our health and welfare plans to the same extent as our full-time employees generally. We generally do not provide our named executive officers with perquisites or other personal benefits. We contract with Trinet, a professional employer organization that helps us administer pay and benefits, among other things.

Retirement Benefits.

We have established a 401(k) tax-deferred savings plan through Trinet, which permits participants, including our named executive officers, to make contributions by salary deduction pursuant to Section 401(k) of the Internal Revenue Code. We are responsible for administrative costs of the 401(k) plan.

Outstanding Equity Awards at 2019 Fiscal Year-End

The following table sets forth information regarding each unexercised option and all unvested stock held by each of our named executive officers as of December 31, 2019.

The vesting schedule applicable to each outstanding award is described in the footnotes to the table below.

Name	Option Awards			
	Number of Securities Underlying Unexercised Options Vested (#)	Number of Securities Underlying Unexercised Options Unvested (#)	Option Exercise Price (\$)	Option Expiration Date
Bobak Azamian	266,685(1)	586,708(1)	\$ 0.06	10/26/2028
Mark Holdbrook	432,291(2)	190,209(2)	\$0.0001	11/28/2027

(1) Option vests in 48 substantially equal monthly installments beginning on September 15, 2018 provided Dr. Azamian remains in continuous service through each such vesting date. The option will also become fully vested on an accelerated basis if Dr. Azamian remains in continuous service through a change in control.

(2) Option vests in 36 substantially equal monthly installments beginning on November 1, 2017, provided Mr. Holdbrook remains in continuous service through each such vesting date. The option will also become fully vested on an accelerated basis if Mr. Holdbrook remains in continuous service through a change in control.

Severance and Change in Control Benefits

The restricted shares and option to purchase shares of our Common Stock held by Dr. Azamian fully vest in the event we are subject to a change in control. Change in control means our consummation of a merger or consolidation with or into another entity or our dissolution, liquidation or winding up. The foregoing notwithstanding, our merger or consolidation does not constitute a change in control if immediately after the merger or consolidation a majority of the voting power of the capital stock of the continuing or surviving entity, or any direct or indirect parent corporation of the continuing or surviving entity, will be owned by the persons who were our stockholders immediately prior to the merger or consolidation in substantially the same proportions as their ownership of the voting power of our capital stock immediately prior to the merger or consolidation.

Neither Dr. Azamian nor Mr. Holdbrook are eligible for any severance benefits.

Equity Plans

2020 Equity Incentive Plan

Our board of directors intends to adopt our 2020 Plan prior to the offering, and it will be submitted to our stockholders for approval. We expect that our 2020 Plan will become effective immediately on adoption although no awards will be made under it until the effective date of the registration statement of which this prospectus is a part. Our 2020 Plan is intended to replace our 2016 Plan. However, awards outstanding under our 2016 Plan will continue to be governed by their existing terms. Although not yet adopted, we expect that our 2020 Plan will have the features described below.

Share Reserve. The number of shares of our common stock available for issuance under our 2020 Plan will equal the sum of shares plus up to shares remaining available for issuance under our 2016 Plan, or issued pursuant to or subject to awards granted under, our 2016 Plan. The number of shares reserved for issuance under our 2020 Plan will be increased automatically on the first business day of each of our fiscal years, commencing in 2021 and ending in 2030, by a number equal to the smallest of:

- shares;
- % of the shares of common stock outstanding on the last business day of the prior fiscal year; or
- the number of shares determined by our board of directors.

In general, to the extent that any awards under our 2020 Plan are forfeited, terminate, expire or lapse without the issuance of shares, or if we repurchase the shares subject to awards granted under our 2020 Plan, those shares will again become available for issuance under our 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.

Administration. The compensation committee of our board of directors will administer our 2020 Plan. The compensation committee will have complete discretion to make all decisions relating to our 2020 Plan and outstanding awards, including repricing outstanding options and modifying outstanding awards in other ways.

Eligibility. Employees, non-employee directors, consultants and advisors will be eligible to participate in our 2020 Plan.

Under our 2020 Plan, the aggregate grant date fair value of awards granted to our non-employee directors may not exceed \$ in any one fiscal year, except that the grant date fair value of awards granted to newly appointed non-employee directors may not exceed \$ in the fiscal year in which such non-employee director is initially appointed to our board of directors.

Types of Awards. Our 2020 Plan will provide for the following types of awards:

- incentive and nonstatutory stock options;
- stock appreciation rights;
- restricted shares; and
- restricted stock units.

Table of Contents

Options and Stock Appreciation Rights. The exercise price for options granted under our 2020 Plan may not be less than 100% of the fair market value of our common stock on the grant date. Optionees will be permitted to pay the exercise price in cash or, with the consent of the compensation committee:

- with shares of common stock that the optionee already owns;
- by an immediate sale of shares through a broker approved by us;
- by instructing us to withhold a number of shares having an aggregate fair market value that does not exceed the exercise price; or
- by other methods permitted by applicable law.

An optionee who exercises a stock appreciation right receives the increase in value of our common stock over the base price. The base price for stock appreciation rights may not be less than 100% of the fair market value of our common stock on the grant date. The settlement value of a stock appreciation right may be paid in cash, shares of our common stock or a combination.

Options and stock appreciation rights vest as determined by the compensation committee. In general, they will vest over a four-year period following the date of grant. Options and stock appreciation rights expire at the time determined by the compensation committee but in no event more than ten years after they are granted. These awards generally expire earlier if the participant's service terminates earlier.

Restricted Shares and Stock Units. Restricted shares and stock units may be awarded under our 2020 Plan in return for any lawful consideration, and participants who receive restricted shares or stock units generally are not required to pay cash for their awards. In general, these awards will be subject to vesting. Vesting may be based on length of service, the attainment of performance-based milestones or a combination of both, as determined by the compensation committee.

Corporate Transactions. In the event we are a party to a merger, consolidation or certain change in control transactions, outstanding awards granted under our 2020 Plan, and all shares acquired under our 2020 Plan, will be subject to the terms of the definitive transaction agreement (or, if there is no such agreement, as determined by our compensation committee). Unless an award agreement provides otherwise, such treatment may include any of the following with respect to each outstanding award:

- the continuation, assumption or substitution of an award by a surviving entity or its parent;
- the cancellation of an award without payment of any consideration, provided that the optionee shall be notified of such treatment;
- the cancellation of the vested portion of an award (and any portion that becomes vested as of the effective time of the transaction) in exchange for a payment equal to the excess, if any, of the value that the holder of each share of our common stock receives in the transaction over (if applicable) the exercise price otherwise payable in connection with the award; or
- the assignment of any reacquisition or repurchase rights held by us with respect to an award of restricted shares to the surviving entity or its parent (with proportionate adjustments made to the price per share to be paid upon exercise of such rights).

The compensation committee is not required to treat all awards, or portions thereof, in the same manner.

Table of Contents

The vesting of an outstanding award may be accelerated by the administrator upon the occurrence of a change in control, whether or not the award is to be assumed or replaced in the transaction, or in connection with a termination of service following a change in control transaction.

A change in control includes:

- any person acquiring beneficial ownership of more than 50% of our total voting power;
- the sale or other disposition of all or substantially all of our assets; or
- our merger or consolidation after which our voting securities represent 50% or less of the total voting power of the surviving or acquiring entity.

Changes in Capitalization. In the event of certain changes in our capital structure without our receipt of consideration, such as a stock split, reverse stock split or dividend paid in common stock, proportionate adjustments will automatically be made to:

- the maximum number and kind of shares available for issuance under our 2020 Plan, including the maximum number and kind of shares that may be issued upon the exercise of incentive stock options;
- the maximum number and kind of shares covered by, and exercise price, base price or purchase price, if any, applicable to each outstanding stock award; and
- the maximum number and kind of shares by which the share reserve may increase automatically each year.

In the event that there is a declaration of an extraordinary dividend payable in a form other than our common stock in an amount that has a material effect on the price of our common stock, a recapitalization, a spin-off or a similar occurrence, the compensation committee may make such adjustments to any of the foregoing as it deems appropriate, in its sole discretion.

Amendments or Termination. Our board of directors may amend, suspend or terminate our 2020 Plan at any time. If our board of directors amends our 2020 Plan, it does not need stockholder approval of the amendment unless required by applicable law, regulation or rules. Our 2020 Plan will terminate automatically 10 years after the later of the date when our board of directors adopted our 2020 Plan or approved the latest share increase that was also approved by our stockholders.

2016 Stock Plan

Our board of directors adopted our 2016 Stock Plan in December 2016, and it was approved by our stockholders on January 17, 2017. No further awards will be made under our 2016 Plan after this offering; however, awards outstanding under our 2016 Plan will continue to be governed by their existing terms.

Share Reserve. As of December 31, 2019, we have reserved 19,832,815 shares of our common stock for issuance under our 2016 Plan, all of which may be issued as incentive stock options. As of December 31, 2019, options to purchase 2,207,154 shares of our common stock, at exercise prices ranging from \$0.0001 to \$0.06 per share, or a weighted-average exercise price of \$0.04 per share were outstanding under our 2016 Plan, and 15,975,661 shares of our common stock remained available for future issuance. Unissued shares subject to awards that expire or are cancelled, shares reacquired by us and shares withheld in payment of the purchase price or exercise price of an award or in satisfaction of withholding taxes will again become available for issuance under our 2016 Plan or, following consummation of this offering, under our 2020 Plan.

[Table of Contents](#)

Administration. Our board of directors has administered our 2016 Plan since its adoption; however, following this offering, the compensation committee of our board of directors will generally administer our 2016 Plan. The administrator has complete discretion to make all decisions relating to our 2016 Plan and outstanding awards.

Eligibility. Employees, non-employee members of our board of directors and consultants are eligible to participate in our 2016 Plan. However, only employees are eligible to receive incentive stock options.

Types of Awards. Our 2016 Plan provides for the following types of awards granted with respect to shares of our common stock:

- incentive and nonstatutory stock options to purchase shares of our common stock; and
- direct award or sale of shares of our common stock, including restricted shares.

Options. The exercise price for options granted under our 2016 Plan is determined by our board of directors, but may not be less than 100% of the fair market value of our common stock on the grant date. Optionees may pay the exercise price in cash or cash equivalents or by one, or any combination of, the following forms of payment, as permitted by the administrator in its sole discretion:

- Surrender of shares of common stock that the optionee already owns;
- Delivery of a full-recourse promissory note, with the option shares pledged as security against the principal and accrued interest on the note;
- An immediate sale of the option shares through a company-approved broker, if the shares of our common stock are publicly traded;
- Surrendering a number of vested shares subject to the option having an aggregate fair market value no greater than the aggregate exercise price, or the sum of such exercise price plus all or a portion of the minimum amount required to be withheld under applicable law; or
- Other methods permitted by the Delaware General Corporation Law, as amended.

Options vest as determined by the administrator. In general, we have granted options that vest over a four-year period. Options expire at the time determined by the administrator, but in no event more than ten years after they are granted, and generally expire earlier if the optionee's service terminates.

Restricted Shares. Restricted shares may be awarded or sold under our 2016 Plan in return for cash or cash equivalents or, as permitted by the administrator in its sole discretion, in exchange for services rendered to us, by delivery of a full-recourse promissory note or through any other means permitted by applicable law. Restricted shares vest as determined by the administrator.

Corporate Transactions. In the event that we are a party to a merger or consolidation or in the event of a sale of all or substantially all of our stock or assets, awards granted under our 2016 Plan will be subject to the agreement governing such transaction or, in the absence of such agreement, in the manner determined by the administrator. Such treatment may include, without limitation, one or more of the following with respect to outstanding awards:

- The continuation, assumption or substitution of an award by the surviving entity or its parent;
- Cancellation of the vested portion of the award in exchange for a payment equal to the excess, if any, of the value of the shares subject to the award over any exercise price per share applicable to the award;

Table of Contents

- Cancellation of the award without payment of any consideration;
- Suspension of the optionee's right to exercise the option during a limited period of time preceding the completion of the transaction;
or
- Termination of any right the optionee has to exercise the option prior to vesting in the shares subject to the option.

The administrator is not obligated to treat all awards in the same manner. The administrator has the discretion, at any time, to provide that an award under our 2016 Plan will vest on an accelerated basis in connection with a corporate transaction or to amend or modify an award so long as such amendment or modification is not inconsistent with the terms of the 2016 Plan or would not result in the impairment of a participant's rights without the participant's consent.

Changes in Capitalization. In the event of certain specified changes in the capital structure of our common stock, such as a stock split, reverse stock split, stock dividend, reclassification or any other increase or decrease in the number of issued shares of stock effective without receipt of consideration by us, proportionate adjustments will automatically be made in (i) each of the number and kind of shares available for future grants under our 2016 Plan, (ii) the number and kind of shares covered by each outstanding option and all restricted shares, (iii) the exercise price per share subject to each outstanding option and (iv) any repurchase price applicable to shares granted under our 2016 Plan. In the event of an extraordinary cash dividend that has a material effect on the fair market value of our common stock, a recapitalization, spin-off or other similar occurrence, the administrator at its sole discretion may make appropriate adjustments to one or more of the items described above.

Amendments or Termination. The administrator may at any time amend, suspend or terminate our 2016 Plan, subject to stockholder approval in the case of an amendment if the amendment increases the number of shares available for issuance or materially changes the class of persons eligible to receive incentive stock options. Our 2016 Plan will terminate automatically ten years after the later of the date when our board of directors adopted the plan or the date when our board of directors most recently approved an increase in the number of shares reserved thereunder which was also approved by our stockholders, provided, however, that in any event, it will terminate upon the completion of this offering, but as noted above, awards outstanding under our 2016 Plan will remain outstanding and will continue to be governed by their existing terms.

Employee Stock Purchase Plan

General. We expect that our board of directors will adopt a 2020 ESPP prior to this offering. If adopted, our 2020 ESPP will be subsequently approved by our stockholders. We expect that our 2020 ESPP will become effective as of the effective date of the registration statement of which this prospectus is a part. Our 2020 ESPP is intended to qualify under Section 423 of the Internal Revenue Code. Although not yet adopted, we expect that our 2020 ESPP will have the features described below.

Share Reserve. _____ shares of our common stock will be reserved for issuance under our 2020 ESPP. The number of shares reserved for issuance under our 2020 ESPP will automatically be increased on the first business day of each of our fiscal years, commencing in 2021 and ending in 2040, by a number equal to the least of:

- _____ shares;
- _____ % of the shares of common stock outstanding on the last business day of the prior fiscal year; or
- the number of shares determined by our board of directors.

[Table of Contents](#)

The number of shares reserved under our 2020 ESPP will automatically be adjusted in the event of a stock split, stock dividend or a reverse stock split (including an adjustment to the per-purchase period share limit).

Administration. The compensation committee of our board of directors will administer our 2020 ESPP.

Eligibility. All of our employees will be eligible to participate if we employ them for more than 20 hours per week and for five or more months per year. Eligible employees may begin participating in our 2020 ESPP at the start of any offering period.

Offering Periods. Each offering period will last a number of months determined by the compensation committee, not to exceed 27 months. A new offering period will begin periodically, as determined by the compensation committee. Offering periods may overlap or may be consecutive. Unless otherwise determined by the compensation committee, two offering periods of six months' duration will begin in each year on May 1 and November 1. However, if so determined by the compensation committee, the first offering period may start on the effective date of the registration statement related to this offering and will end on _____, 2021, with the first purchase date occurring on _____, 2021.

Amount of Contributions. Our 2020 ESPP will permit each eligible employee to purchase common stock through payroll deductions. Each employee's payroll deductions may not exceed 15% of the employee's cash compensation. Each participant may purchase up to the number of shares determined by our board of directors on any purchase date, not to exceed _____ shares. The value of the shares purchased in any calendar year may not exceed \$25,000. Participants may withdraw their contributions at any time before stock is purchased.

Purchase Price. The price of each share of common stock purchased under our 2020 ESPP will not be less than 85% of the lower of the fair market value per share of common stock on the first day of the applicable offering period (or, in the case of the first offering period, the price at which one share of common stock is offered to the public in this offering) or the fair market value per share of common stock on the purchase date.

Other Provisions. Employees may end their participation in our 2020 ESPP at any time. Participation ends automatically upon termination of employment with us. If we experience a change in control, our 2020 ESPP will end and shares will be purchased with the payroll deductions accumulated to date by participating employees. Our board of directors or our compensation committee may amend or terminate our 2020 ESPP at any time.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2017 to which we have been a party in which the amount involved exceeded \$120,000 and in which any of our executive officers, directors or beneficial holders of more than 5% of our capital stock (or any immediate family member of, or person sharing the household with, any of these individuals or entities), which we collectively refer to as a related person, had or will have a direct or indirect material interest, other than compensation arrangements which are described in “Management — Director Compensation” and “Executive Compensation.” We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Sales of Securities***Sale of Common Stock***

From January 2017 to March 2018, we issued and sold an aggregate of 19,890,000 shares of our common stock at a cash purchase price of \$0.0001 per share for an aggregate purchase price of approximately \$1,989.00.

The following table sets forth the number of shares of our common stock sold to our directors, executive officers and holders of more than 5% of our capital stock:

<u>Investor</u>	<u>Affiliated Director(s) or Officer(s)</u>	<u>Shares of Common Stock</u>	<u>Total Purchase Price</u>
Bobak Azamian	Bobak Azamian	9,000,000	\$ 900.00
Michael Ackermann	Michael Ackermann	9,000,000	\$ 900.00
William J. Link	William J. Link	1,000,000	\$ 100.00

Series A Preferred Stock Financing

In March and May 2018, we issued and sold an aggregate of 11,698,716 shares of our Series A Preferred Stock at a cash purchase price of \$0.312 per share for an aggregate purchase price of approximately \$3.6 million. These shares of Series A Preferred Stock will convert into an aggregate of 11,698,716 shares of Common Stock upon the completion of this offering.

The following table summarizes purchases of shares of our Series A Preferred Stock by our executive officers, directors and holders of more than 5% of our capital stock:

<u>Investor</u>	<u>Affiliated Director(s) or Officer(s)</u>	<u>Shares of Series A Preferred Stock</u>	<u>Total Purchase Price</u>
Entities affiliated with Horowitz Limited Partnership VIII (1)	Jason Tester	10,977,563	\$ 3,424,999.66
Entities Affiliated with Jason Tester (2)	Jason Tester	160,256	\$ 49,999.97
Michael Ackermann	Michael Ackermann	400,641	\$ 125,000.00
Bobak Azamian	Bobak Azamian	160,256	\$ 49,999.87

(1) Entities affiliated with the Horowitz Limited Partnership VIII, who purchased shares of Series A Preferred Stock include the Horowitz Limited Partnership VIII and the Adam S Horowitz Revocable Trust. Jason Tester is an affiliate of Horowitz Limited Partnership VIII.

(2) Entities affiliated with the Jason Tester who purchased shares of Series A Preferred Stock includes the Tester Living Trust.

2019 Convertible Notes

Throughout 2019, we issued various convertible notes with an aggregate principle amount of \$2.0 million, or the 2019 Notes. All principal and interest accrued under the 2019 Notes was converted at various discounts into shares of Series B Preferred Stock in connection with the closing of our Series B preferred stock financing in December 2019.

Table of Contents

The following table sets forth the aggregate principal amount plus accrued interest of the 2019 Notes that was converted, the number of shares of Series B Preferred Stock issued upon conversion of such notes to our executive officers, directors and holders of more than 5% of our capital stock, and their respective affiliates upon conversion of such notes and the aggregate purchase price for such notes:

<u>Investor</u>	<u>Affiliated Director(s) or Officer(s)</u>	<u>Series B Convertible Promissory Note Principal Amount and Interest (\$)</u>	<u>Shares of Series B Preferred Stock</u>
Entities affiliated with Horowitz Limited Partnership VIII (1)	Jason Tester	\$ 1,930,070.20	1,881,896
Entities Affiliated with Jason Tester (2)	Jason Tester	\$ 28,176.15	27,473
Bobak Azamian	Bobak Azamian	\$ 14,162.48	13,001
Michael Ackermann	Michael Ackermann	\$ 70,440.52	68,682

- (1) Entities affiliated with Horowitz Limited Partnership VIII whose convertible promissory notes converted into shares of our Series B Preferred Stock include the Horowitz Limited Partnership VIII and the Adam S Horowitz Revocable Trust. Jason Tester is an affiliate of Horowitz Limited Partnership VIII.
- (2) Entities affiliated with Jason Tester whose convertible promissory notes converted into shares of our Series B Preferred Stock include the Tester Living Trust.

Series B Preferred Stock Financing

In December 2019, we issued and sold an aggregate of 47,587,571 shares of our Series B Preferred Stock (exclusive of 1,991,052 shares issued upon the conversion of the 2019 Notes) at a cash purchase price of \$1.2104 per share for an aggregate purchase price of approximately \$57.6 million. These shares of Series B Preferred Stock, together with the shares issued upon conversion of the 2019 Notes, will convert into an aggregate of 49,578,623 shares of common stock upon the completion of this offering. The table below sets forth the number of shares of Series B Preferred Stock sold to our directors, executive officers and holders of more than 5% of our capital stock (not including the 1,991,052 shares of Series B Preferred Stock issued upon the conversion of the 2019 Notes):

<u>Investor</u>	<u>Affiliated Director(s) or Officer(s)</u>	<u>Shares of Series B Preferred Stock</u>	<u>Total Purchase Price</u>
Vivo Capital Fund IX, L.P.	Andrew Goldberg (1)	20,654,329	\$ 24,999,999.83
Frazier Life Sciences IX, L.P.	Bhaskar Chaudhuri (2)	10,327,164	\$ 12,499,999.31
Flying L Investments XI, LLC	William J. Link	8,261,731	\$ 9,999,999.21
Entities affiliated with Visionary Venture Fund (3)		6,196,298	\$ 7,499,999.11

- (1) Mr. Goldberg was designated by Vivo Capital Fund IX, L.P. but does not have any voting or investment control over the shares held by Vivo Capital Fund IX, L.P.
- (2) Dr. Chaudhuri was designated by Frazier Life Sciences IX, L.P. but does not have any voting or investment control over the shares held by Frazier Life Sciences IX, L.P.
- (3) Entities affiliated with Visionary Venture Fund holding shares of our Series B Preferred Stock which are aggregated for purposes of reporting share ownership information include Visionary Venture Fund II, LP and Visionary Venture Fund II (QP), LP.

Agreements with Stockholders

Investors' Rights Agreement

We are party to an amended and restated investors' rights agreement with (i) certain holders of our capital stock, including entities affiliated with Mr. Tester, (ii) entities affiliated with Visionary Venture Fund, (iii) Vivo Capital Fund IX, L.P., (iv) Frazier Life Sciences IX, L.P., (v) Flying L Investments XI, LLC, (vi) Michael Ackermann and (vii) Dr. Azamian. Under our investors' rights agreement, certain holders of our capital stock have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing. See the section titled "Description of Capital Stock — Registration Rights" elsewhere in this prospectus for additional information regarding these registration rights.

[Table of Contents](#)

Voting Agreement

We are party to an amended and restated voting agreement with certain holders of our capital stock, including (i) entities affiliated with Mr. Tester, (ii) entities affiliated with Visionary Venture Fund, (iii) Vivo Capital Fund IX, L.P., (iv) Frazier Life Sciences IX, L.P., (v) Flying L Investments XI, LLC, (vi) Michael Ackermann and (vii) Dr. Azamian. Under our voting agreement, certain holders of our capital stock have agreed as to the manner in which they will vote their shares of our capital stock on certain matters, including with respect to the election of directors. The voting agreement will terminate upon the completion of this offering, at which time there will be no further contractual obligations regarding the manner in which shares are voted with respect to the election of our directors.

Right of First Refusal and Co-Sale Agreement

We are party to an amended and restated first refusal and co-sale agreement with certain holders of our capital stock, including (i) entities affiliated with Mr. Tester, (ii) entities affiliated with Visionary Venture Fund, (iii) Vivo Capital Fund IX, L.P., (iv) Frazier Life Sciences IX, L.P., (v) Flying L Investments XI, LLC, (vi) Michael Ackermann and (vii) Dr. Azamian. Under our first refusal and co-sale agreement, certain holders of our capital stock have the right of first refusal and co-sale relating to the shares of our common stock held by the parties to the agreement. Upon the consummation of this offering our first refusal and co-sale agreement will terminate.

Indemnification Agreements

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and our restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law. See the section titled “Executive Compensation — Limitation of Liability and Indemnification” elsewhere in this prospectus for additional information.

Related Party Transaction Policy

Prior to the completion of this offering, we intend to adopt a formal written policy providing that we are not permitted to enter into any transaction that exceeds \$120,000 and in which any related person has a direct or indirect material interest without the consent of our audit committee. Our audit committee will have the primary responsibility for reviewing and approving or disapproving such “related party transactions.” The charter of our audit committee will provide that our audit committee shall review and approve in advance any related party transaction. In approving or rejecting any such transaction, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to our audit committee, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person’s interest in the transaction.

All of the transactions described in this section were entered into prior to the adoption of this policy. Although we have not had a written policy for the review and approval of transactions with related persons, our board of directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including the transactions described above. Prior to approving such a transaction, the material facts as to relationship or interest of the relevant director, officer or holder of 5% or more of any class of our voting securities in the agreement or transaction was disclosed to our board of directors. Our board of directors took this information into account when evaluating the transaction and in determining whether such transaction was fair to us and in the best interest of all our stockholders.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of June 30, 2020 and as adjusted to reflect the sale of common stock offered by us in this offering, for:

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

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on _____ shares of common stock outstanding as of June 30, 2020, after giving effect to the conversion of all outstanding shares of preferred stock as of that date into an aggregate of _____ shares of our common stock. For purposes of computing percentage ownership after this offering, we have assumed that (i) _____ shares of common stock will be issued by us in this offering; (ii) the underwriters will not exercise their option to purchase up to _____ additional shares and (iii) none of our executive officers, directors or stockholders who beneficially own more than five percent of our common stock will participate in this offering. In computing the number of shares of common stock beneficially owned by a person or entity and the percentage ownership of that person or entity, we deemed to be outstanding all shares of common stock subject to options held by that person or entity that are currently exercisable or that will become exercisable within 60 days of June 30, 2020. We did not deem these shares outstanding, however, such shares were included for the purpose of computing the percentage ownership of any other person or entity.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Tarsus Pharmaceuticals, Inc., 15440 Laguna Canyon Road, Irvine, California 92618.

Name of Beneficial Owner	Shares Beneficially Owned Prior to this Offering		Shares Beneficially Owned After this Offering	
	Shares	Percentage	Shares	Percentage
Named Executive Officers and Directors:				
Bobak Azamian (1)	10,266,193	12.43%		
Michael Ackermann (2)	9,127,966	11.20%		
Jason Tester (3)	12,671,731	15.55%		
Andrew Goldberg	—	— %		
William J. Link (5)	9,261,731	11.37%		
Bhaskar Chaudhuri	—	— %		
Leo M. Greenstein (6)	870,370	1.06%		
Seshadri Neervannan	—	—		
Mark Holdbrook (7)	582,550	*		
All executive officers and directors as a group (9 persons) (8)	42,780,541	51.22%		
5% Stockholders:				
Entities affiliated with Horowitz Limited Partnership VIII (9)	12,859,459	15.78%		
Vivo Capital Fund IX, L.P. (4)	20,654,329	25.35%		
Flying L Investments XI, LLC (10)	8,261,731	10.14%		
Frazier Life Sciences IX, L.P. (11)	10,327,164	12.68%		
Visionary Venture Fund (12)	6,196,298	7.61%		

Table of Contents

- * Represents beneficial ownership of less than one percent.
- (1) Consists of (i) 13,001 shares of common stock held directly by Dr. Azamian (ii) 1,092,936 shares of common stock issuable pursuant to options held directly by Dr. Azamian exercisable within 60 days of June 30, 2020, and (iii) 9,160,256 shares of common stock held by Bobak Azamian, as Trustee of the Bobak Azamian Living Trust, established April 16, 2018. Dr. Azamian is a trustee the Bobak Azamian Living Trust, established April 16, 2018 and has voting and investment control with respect to these shares.
 - (2) Consists of 9,127,966 shares of common stock held directly by Dr. Ackermann.
 - (3) Consists of (i) 12,484,002 shares of common stock held by Horowitz Limited Partnership VIII (ii) 187,729 shares of common stock held by the Tester Living Trust. Mr. Tester is a trustee of the Tester Living Trust, and has voting and investment control with respect to these shares. Mr. Tester is the Chief Financial Officer of Horowitz Management, Inc., the managing partner of Horowitz Limited Partnership VIII, and in his capacity as such, Mr. Tester may be deemed to have shared voting and or investment power over the shares held by Horowitz Limited Partnership VIII. Mr. Tester disclaims beneficial ownership of the shares held by Horowitz Limited Partnership VIII. Mr. Tester disclaims beneficial ownership of the shares held by Horowitz Limited Partnership VIII.
 - (4) Consists of 20,654,329 shares of common stock held of record by Vivo Capital Fund IX, L.P. Vivo Capital IX, LLC is the general partner of Vivo Capital Fund IX, L.P. The voting members of Vivo Capital IX, LLC are Frank Kung, Albert Cha, Edgar Engleman, Shan Fu and Chen Yu. None of such voting members have individual voting or investment power with respect to these shares and each of whom disclaims beneficial ownership of such shares. The principal business address of Vivo Capital IX, LLC is 192 Lytton Avenue, Palo Alto, CA 94301.
 - (5) Consists of (i) 1,000,000 shares of common stock held directly by Dr. Link and (ii) 8,261,731 shares of common stock owned by Flying L Investments XI, LLC. Dr. Link is the Manager of Flying L Investments XI, LLC, and in his capacity as such, Dr. Link may be deemed to have sole voting and investment power over shares held by Flying L Investments XI, LLC. Dr. Link disclaims beneficial ownership of the shares held by Flying L Investments XI, LLC except to the extent of his pecuniary interest in such shares.
 - (6) Consists of 500,000 shares of common stock held directly by Mr. Greenstein and 370,370 shares of common stock issuable pursuant to options held directly by Mr. Greenstein exercisable within 60 days of June 30, 2020.
 - (7) Consists of 582,550 shares of common stock issuable pursuant to options held directly by Mr. Holdbrook exercisable within 60 days of June 30, 2020.
 - (8) See footnotes (1) through (7) above.
 - (9) Consists of (i) 12,484,002 shares of common stock held by Horowitz Limited Partnership VIII and (ii) 375,457 shares of common stock held by Adam S. Horowitz Revocable Trust. Mr. Tester is the Chief Financial Officer of Horowitz Management, Inc., the managing partner of Horowitz Limited Partnership VIII, and in his capacity as such, Mr. Tester may be deemed to have shared voting and or investment power over the shares held by Horowitz Limited Partnership VIII. Mr. Tester disclaims beneficial ownership of the shares held by Horowitz Limited Partnership VIII. Mr. Tester disclaims beneficial ownership of the shares held by the shares held by Horowitz Limited Partnership VIII and Adam S. Horowitz Revocable Trust. The principal business address of Horowitz Limited Partnership VIII is 27241 La Paz Road, Suite B, Laguna Niguel, CA 92677.
 - (10) Consists of 8,261,731 shares of common stock owned by Flying L Investments XI, LLC. Dr. Link is the Manager of Flying L Investments XI, LLC, and in his capacity as such, Dr. Link may be deemed to have sole voting and investment power over shares held by Flying L Investments XI, LLC. Dr. Link disclaims beneficial ownership of the shares held by Flying L Investments XI, LLC except to the extent of his pecuniary interest in such shares. The principal business address of Flying L Investments XI, LLC is 11 Linda Isle, Newport Beach, CA 92660.
 - (11) Consists of 10,327,164 shares of common stock owned by Frazier Life Sciences IX, L.P., or FLS LP. The general partner of FLS LP is FHMLS IX, L.P., and the general partner of FHMLS IX, L.P. is FHMLS IX, LLC. James Topper and Patrick J. Heron are the sole managing members of FHMLS IX, LLC, and share voting and investment power with respect to such shares held by FLS LP. Dr. Topper and Mr. Heron disclaim beneficial ownership of such shares except to the extent of their pecuniary interest in such shares. The principal business address of Frazier Life Sciences IX, L.P. is Two Union Square, 601 Union St., Suite 3200, Seattle, WA 98101.
 - (12) Consists of (i) 4,662,095 shares of common stock held by Visionary Venture Fund II (QP), LP and (ii) 1,534,203 shares of common stock owned by Visionary Venture Fund II, LP. VMP Investments, Inc. is the manager of Visionary Venture Fund II, LP and Visionary Venture Fund II (QP). Jeffrey K. Weinhuff is the President of VMP Investments, Inc. and disclaims beneficial ownership of the shares held by Visionary Venture Fund II, LP and Visionary Venture Fund II (QP) except to the extent of his pecuniary interest in such shares. The principal business address of Visionary Venture Fund II, LP is 65 Enterprise, Suite 330, Aliso Viejo, CA 92656.

DESCRIPTION OF CAPITAL STOCK

The following descriptions of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect upon completion of this offering. A description of our capital stock and the material terms and provisions of our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering and affecting the rights of holders of our capital stock is set forth below. The forms of our amended and restated certificate of incorporation and our amended and restated bylaws to be adopted in connection with this offering are filed as exhibits to the registration statement relating to this prospectus.

Upon the completion of this offering, our amended and restated certificate of incorporation will authorize shares of undesignated preferred stock, the rights, preferences and privileges of which may be designated from time to time by our board of directors.

Upon the completion of this offering, our authorized capital stock will consist of _____ shares, all with a par value of \$0.0001 per share, of which:

- _____ shares are designated common stock; and
- _____ shares are designated preferred stock.

As of June 30, 2020, after giving effect to the conversion of all outstanding shares of preferred stock into an aggregate of _____ shares of our common stock, there were outstanding:

- _____ shares of our common stock held of record by 48 stockholders, including _____ shares of restricted common stock that are subject to our right of repurchase; and
- _____ shares of our common stock issuable upon exercise of outstanding stock options.

Common Stock

Dividend Rights

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

Voting Rights

The holders of our common stock are entitled to one vote per share. Stockholders do not have the ability to cumulate votes for the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering will provide for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights and is not subject to conversion, redemption or sinking fund provisions.

[Table of Contents](#)

Right to Receive Liquidation Distributions

Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to our stockholders are distributable ratably among the holders of our common stock, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Preferred Stock

Upon the completion of this offering, no shares of preferred stock will be outstanding, but we will be authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any associated qualifications, limitations or restrictions. Our board of directors also can increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the market price of our common stock and the voting and other rights of the holders of common stock. We have no current plan to issue any shares of preferred stock.

Options

As of June 30, 2020, there were options to purchase _____ shares of our common stock outstanding, all of which were subject to options granted under our 2016 Stock Plan.

Registration Rights

Following the completion of this offering, the holders of _____ shares of our common stock issued upon the conversion of our preferred stock will be entitled to contractual rights to require us to register those shares under the Securities Act. These registration rights are provided under the terms of our amended and restated investors' rights agreement between us and the holders of these shares, which we entered into on December 13, 2019.

We will pay all expenses relating to any demand or piggyback registration described below, other than underwriting discounts and commissions. The registration rights terminate upon the earliest to occur of: (i) the fifth anniversary of the completion of this offering; (ii) a liquidation event; or (iii) with respect to the registration rights of an individual holder, such earlier time after this offering at which the holder (a) can sell all of its shares in compliance with Rule 144(b)(1)(i) or (b) holds one percent or less of our outstanding common stock and all shares held by the holder can be sold in any three-month period without registration in compliance with Rule 144.

Demand Registration Rights

The holders of the registrable securities will be entitled to certain demand registration rights. At any time beginning six months following the effectiveness of this offering, the holders of 30% or more of the registrable securities then outstanding may make a written request that we register some or all of their registrable securities, subject to certain specified conditions and exceptions. We are required to use commercially reasonable efforts to effect the registration and will pay all registration expenses, other than underwriting discounts and commissions, related to any demand registration. Such request for registration must cover securities with an aggregate offering price of at least \$20,000,000. We are not obligated to effect more than two of these registrations.

Table of Contents

Piggyback Registration Rights

In connection with this offering, holders of our registrable securities were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their registrable securities in this offering. If we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders in another offering, the holders of shares having registration rights will, subject to certain exceptions, be entitled to include their shares in our registration statement, provided that the underwriters of any such offering have the right to limit the number of shares included in the registration. These registration rights are subject to specified other conditions and limitations as set forth in our amended and restated investors' rights agreement.

Form S-3 Registration Rights

At any time after we are qualified to file a registration statement on Form S-3, and subject to limitations and conditions specified in the amended and restated investors' rights agreement, the holders of 25% or more of the registrable securities then outstanding may make a written request that we prepare and file a registration statement on Form S-3 under the Securities Act covering their shares, so long as the aggregate price to the public is at least \$10,000,000. We are not obligated to effect more than two of these Form S-3 registrations in any 12-month period. Such holders will pay pro rata all expenses related to filing a registration statement on Form S-3.

Anti-Takeover Provisions

Delaware Law

Upon the completion of this offering, we will be governed by the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. This section prevents some Delaware corporations from engaging, under some circumstances, in a business combination, which includes a merger or sale of at least 10% of the corporation's assets with any interested stockholder, meaning a stockholder who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of the corporation's outstanding voting stock, unless:

- the transaction is approved by the board of directors prior to the time that the interested stockholder became an interested stockholder;
- upon closing of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- subsequent to such time that the stockholder became an interested stockholder the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or amended and restated bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Certificate of Incorporation and Bylaw Provisions

Upon the completion of this offering, our amended and restated certificate of incorporation and our amended and restated bylaws will include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control of our management team, including the following:

- *Board of Directors Vacancies.* Our amended and restated certificate of incorporation and amended and restated bylaws will authorize our board of directors to fill vacant directorships, including newly-created seats. In addition, the number of directors constituting our board of directors will be set only by resolution adopted by a majority vote of our entire board of directors. These provisions will prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.
- *Classified Board.* Our amended and restated certificate of incorporation and amended and restated bylaws will provide that our board of directors will be classified into three classes of directors, each of which will hold office for a three-year term. In addition, directors may only be removed from the board of directors for cause and only by the approval of 66 2/3% of our then-outstanding shares of our common stock. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.
- *Stockholder Action; Special Meeting of Stockholders.* Our amended and restated certificate of incorporation will provide that stockholders will not be able to take action by written consent, and will only be able to take action at annual or special meetings of our stockholders. Stockholders will not be permitted to cumulate their votes for the election of directors. Our amended and restated bylaws will further provide that special meetings of our 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.
- *Advance Notice Requirements for Stockholder Proposals and Director Nominations.* Our amended and restated bylaws will provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at any meeting of stockholders. Our amended and restated bylaws will also specify certain requirements regarding the form and content of a stockholder's notice. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our meetings of stockholders.
- *Issuance of Undesignated Preferred Stock.* Our board of directors will have, the authority, without further action by the holders of common stock, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by the board of directors. The existence of authorized but unissued shares of preferred stock will enable our board of directors to render more difficult or discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

Choice of Forum

Upon the completion of this offering, our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty owed by any of our directors, officers, employees or stockholders to us or our stockholders; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or any action asserting a claim against us that is governed by the internal affairs

Table of Contents

doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions in our certificate of incorporation to be inapplicable or unenforceable. These choice of forum provisions will not apply to claims arising under the Securities Act, the Exchange Act, or any other claim for which federal courts have exclusive jurisdiction. Furthermore, our certificate of incorporation that will become effective upon the closing of this offering provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find such provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be . The transfer agent's address is , and its telephone number is .

Listing

We have applied to list our common stock on the Nasdaq Global Market under the symbol "TARS."

SHARES ELIGIBLE FOR FUTURE SALE

Before this offering, there has not been a public market for shares of our common stock and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of shares of our common stock, including shares issued upon the exercise of outstanding options, in the public market following this offering or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital through sales of equity securities in the future.

Upon the closing of this offering, we will have outstanding _____ shares of our common stock, based on the number of shares outstanding as of _____. This includes _____ shares of common stock that we are selling in this offering, which shares may be resold in the public market immediately unless purchased by our affiliates and assuming no additional exercise of outstanding options other than as described elsewhere in this prospectus and the conversion of all outstanding shares of our preferred stock into an aggregate of _____ shares of our common stock upon the closing of this offering.

Of these shares, all shares sold in this offering will be freely tradable without restriction under the Securities Act, unless purchased by our “affiliates,” as that term is defined in Rule 144 under the Securities Act. The remaining _____ shares of common stock that are not sold in this offering will be “restricted securities,” as that term is defined in Rule 144 under the Securities Act, and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements as described below. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which are summarized below.

In addition, we, our executive officers and directors, and all of our other security holders have entered into market standoff agreements with us or lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our capital stock until at least 180 days after the date of this prospectus, as described below. As a result of these agreements and the provisions of our investors’ rights agreement disclosed in “Description of Capital Stock—Registration Rights,” subject to the provisions of Rule 144 or Rule 701, _____ shares will be available for sale in the public market as follows:

- beginning on the date of this prospectus, _____ shares sold in this offering will be immediately available for sale in the public market, unless purchased by our affiliates;
- beginning 181 days after the date of this prospectus, _____ additional shares will become eligible for sale in the public market, of which _____ shares will be held by affiliates and subject to the volume and other restrictions of Rule 144, as described below; and
- the remainder of the shares will be eligible for sale in the public market from time to time thereafter, subject in some cases to the volume and other restrictions of Rule 144, as described below.

We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Rule 144

In general, under Rule 144 as currently in effect, a person who has beneficially owned shares of our restricted common stock for at least six months would be entitled to sell their securities provided that such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale, and we are subject to the periodic reporting requirements of the Exchange Act, for at least 90 days before the

Table of Contents

sale. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the completion of this offering without regard to whether current public information about us is available. Persons who have beneficially owned shares of our restricted common stock for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

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

provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Any of our employees, directors, officers, consultants, advisors or service providers, other than a person who is deemed to have been one of our affiliates during the immediately preceding 90 days, who purchased shares under a written compensatory plan or contract prior to this offering may be entitled to rely on the resale provisions of Rule 701. Rule 701, as currently in effect, permits resales of shares, in reliance upon Rule 144 but without compliance with certain restrictions, including the holding period requirement, of Rule 144. Rule 701 further provides that non-affiliates may sell such shares in reliance on Rule 144 without having to comply with the public information, volume limitation or notice provisions of Rule 144. All holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling such shares if such resale is pursuant to Rule 701. All Rule 701 shares are, however, subject to lock-up agreements and will only become eligible for sale upon the expiration of these lock-up agreements.

Lock-Up Agreements

In connection with this offering, we and each of our directors and officers and all of our other security holders have agreed that, without the prior written consent of BofA Securities, Inc. and Jefferies LLC, on behalf of the underwriters, we and they will not, subject to certain exceptions, during the period ending 180 days after the date of this prospectus:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, shares of our common stock or any securities convertible into or exchangeable for shares of our common stock whether now owned or hereafter acquired or with respect to which such holder has or acquires the power of disposition, of the Lock-up Securities;
- enter into any swap or other agreement or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of the Lock-up Securities, whether any such swap or transaction is to be settled by delivery of our common stock or such other securities, in cash or otherwise; or
- publicly disclose the intention to do any of the foregoing.

[Table of Contents](#)

Each of our directors and executive officers and the holders of substantially all of our outstanding stock and stock options have also agreed during such 180-period not to make any demand for, or exercise any right with respect to, or confidentially submit or cause to be filed or confidentially submitted any registration statement under the Securities Act with respect to, the registration of shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, or warrants or other rights to purchase shares of our common stock or any such securities.

Certain of our employees, including our executive officers, and directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to our initial public offering described above.

Registration Rights

Under our amended and restated investors' rights agreement, after the completion of this offering, the holders of up to _____ shares of our common stock will, subject to the lock-up agreements referred to above, be entitled to certain rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. The registration of these shares of our common stock under the Securities Act would result in these shares becoming eligible for sale in the public market without restriction under the Securities Act immediately upon the effectiveness of such registration, subject to the Rule 144 limitations applicable to affiliates. See the section titled "Description of Capital Stock—Registration Rights" for a description of these registration rights.

Equity Plans

As of June 30, 2020, we had outstanding options to purchase an aggregate of _____ shares of our common stock under the 2016 Plan. Following this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to options outstanding or reserved for issuance under the 2016 Plan, the 2020 Plan and the 2020 ESPP. We expect to file this registration statement as soon as practicable after the completion of this offering. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. For a more complete discussion of our stock plans, see "Executive Compensation—Equity Plans."

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES
FOR NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following is a general discussion of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock (other than an entity or arrangement that is treated as a partnership for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes, any of the following:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in the United States or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more “U.S. persons,” as defined under the Code, have the authority to control all substantial decisions of the trust or (ii) such trust has made a valid election to be treated as a U.S. person for U.S. federal income tax purposes.

This discussion is based on current provisions of the Code, existing, temporary and proposed Treasury Regulations promulgated thereunder, judicial opinions, published positions of the Internal Revenue Service or, the IRS, and other applicable authorities, all of which are subject to change or to differing interpretation, possibly with retroactive effect. This discussion assumes that a non-U.S. holder holds shares of our common stock as a capital asset (generally, property held for investment) for U.S. federal income tax purposes. This discussion does not address all aspects of U.S. federal income taxation that may be important to a particular non-U.S. holder in light of that non-U.S. holder’s individual circumstances, nor does it address any aspects of the unearned income Medicare contribution tax pursuant to the Health Care and Education Reconciliation Act of 2010, any U.S. gift taxes, any U.S. alternative minimum taxes or any state, local or non-U.S. taxes. This discussion may not apply, in whole or in part, to particular non-U.S. holders in light of their individual circumstances or to holders subject to special treatment under the U.S. federal income tax laws (such as insurance companies, tax-exempt organizations, financial institutions, brokers or dealers in securities, “controlled foreign corporations,” “passive foreign investment companies,” non-U.S. holders that hold our common stock as part of a straddle, hedge, conversion transaction or other integrated investment and certain U.S. expatriates). If a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner therein will generally depend on the status of the partner and the activities of the partnership. Partners of a partnership holding our common stock should consult their tax advisor as to the particular U.S. federal income tax consequences applicable to them.

INVESTORS CONSIDERING THE PURCHASE OF OUR COMMON STOCK SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME AND ESTATE TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE CONSEQUENCES OF NON-U.S., STATE, OR LOCAL LAWS AND TAX TREATIES.

Dividends

We do not expect to declare or make any distributions on our common stock in the foreseeable future. If we do pay dividends on shares of our common stock, however, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as

[Table of Contents](#)

determined under U.S. federal income tax principles. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a non-U.S. holder's adjusted tax basis in shares of our common stock. Any excess will be treated as capital gain and will be subject to the treatment described below under "—Gain on Sale or Other Disposition of Common Stock." Any distributions will also be subject to the discussion below under "—Backup Withholding and Information Reporting" and "—Foreign Account Tax Compliance Act."

Any dividend paid to a non-U.S. holder on our common stock that is not effectively connected with a non-U.S. holder's conduct of a trade or business in the United States will generally be subject to U.S. withholding tax at a 30% rate. The withholding tax might apply at a reduced rate, however, under the terms of an applicable income tax treaty between the United States and the non-U.S. holder's country of residence. You should consult your own tax advisors regarding your entitlement to benefits under a relevant income tax treaty. Generally, in order for us or our paying agent to withhold tax at a lower treaty rate, a non-U.S. holder must certify its entitlement to treaty benefits. A non-U.S. holder generally can meet this certification requirement by providing an IRS Form W-8BEN, W-8BENE or other appropriate form (or any successor or substitute form thereof) to us or our paying agent. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to the holder's agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the IRS in a timely manner.

Dividends received by a non-U.S. holder that are effectively connected with a U.S. trade or business conducted by the non-U.S. holder, and if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, are attributable to a permanent establishment maintained by the non-U.S. holder in the United States, are not subject to U.S. withholding tax. To obtain this exemption, a non-U.S. holder must provide us or our paying agent with an IRS Form W-8ECI properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition to being taxed at graduated tax rates, dividends received by a corporate non-U.S. holder that are effectively connected with a U.S. trade or business of the corporate non-U.S. holder may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable tax treaty.

Gain on Sale or Other Disposition of Common Stock

Subject to the discussion below under "—Backup Withholding and Information Reporting" and "—Foreign Account Tax Compliance Act," non-U.S. holders will generally not be subject to U.S. federal income tax on any gains realized on the sale, exchange or other disposition of our common stock unless:

- the gain (i) is effectively connected with the conduct by the non-U.S. holder of a U.S. trade or business and (ii) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States (in which case the special rules described below apply);
- the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale, exchange or other disposition of our common stock, and certain other requirements are met (in which case the gain would be subject to a flat 30% tax, or such reduced rate as may be specified by an applicable income tax treaty, which may be offset by U.S. source capital losses, even though the individual is not considered a resident of the United States); or
- the rules of the Foreign Investment in Real Property Tax Act, or FIRPTA, treat the gain as effectively connected with a U.S. trade or business.

[Table of Contents](#)

The FIRPTA rules may apply to a sale, exchange or other disposition of our common stock if we are, or were within the shorter of the five-year period preceding the disposition and the non-U.S. holder's holding period, a "U.S. real property holding corporation," or USRPHC. In general, we would be a USRPHC if interests in U.S. real estate comprised at least half of the value of our business assets. We do not believe that we are a USRPHC and we do not anticipate becoming one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the non-U.S. holder's holding period.

If any gain from the sale, exchange or other disposition of our common stock, (i) is effectively connected with a U.S. trade or business conducted by a non-U.S. holder and (ii) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment maintained by such non-U.S. holder in the United States, then the gain generally will be subject to U.S. federal income tax at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. If the non-U.S. holder is a corporation, under certain circumstances, that portion of its earnings and profits that is effectively connected with its U.S. trade or business, subject to certain adjustments, generally would be subject also to a "branch profits tax" at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to, and the tax withheld with respect to, each non-U.S. holder. These reporting requirements apply regardless of whether withholding was reduced or eliminated by an applicable tax treaty. Copies of this information reporting may also be made available under the provisions of a specific tax treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established.

A non-U.S. holder will generally be subject to backup withholding for dividends on our common stock paid to such holder unless such holder certifies under penalties of perjury that, among other things, it is a non-U.S. holder (and the payer does not have actual knowledge or reason to know that such holder is a U.S. person) or otherwise establishes an exemption.

Information reporting and backup withholding generally are not required with respect to the amount of any proceeds from the sale or other disposition of our common stock by a non-U.S. holder outside the United States through a foreign office of a foreign broker that does not have certain specified connections to the United States. However, if a non-U.S. holder sells or otherwise disposes of its shares of common stock through a U.S. broker or the U.S. offices of a foreign broker, the broker will generally be required to report the amount of proceeds paid to the non-U.S. holder to the IRS and impose backup withholding on that amount unless such non-U.S. holder provides appropriate certification to the broker of its status as a non-U.S. holder (and the payer does not have actual knowledge or reason to know that such holder is a U.S. person) or otherwise establishes an exemption.

Backup withholding is not an additional income tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder generally can be credited against the non-U.S. holder's U.S. federal income tax liability, if any, or refunded, provided that the required information is furnished to the IRS in a timely manner. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Foreign Account Tax Compliance Act

Under the Foreign Account Tax Compliance Act, or FATCA, withholding tax of 30% applies to certain payments to foreign financial institutions, investment funds and certain other non-U.S. persons that fail to comply with certain information reporting and certification requirements pertaining to their direct and indirect U.S. securityholders and/or U.S. accountholders and do not otherwise qualify for an exemption. Under applicable Treasury Regulations and IRS guidance, this withholding currently applies to payments of dividends, if any, on, and, subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, our common stock. An intergovernmental agreement between the United States and a foreign country may modify the requirements described in this paragraph.

While, beginning on January 1, 2019, withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

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

Federal Estate Tax

Common stock we have issued that is owned (or treated as owned) by an individual who is not a citizen or a resident of the United States (as defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes unless an applicable estate or other tax treaty provides otherwise, and therefore may be subject to U.S. federal estate tax.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE POTENTIAL APPLICATION OF WITHHOLDING UNDER FATCA TO THEIR INVESTMENT IN OUR COMMON STOCK. THE PRECEDING DISCUSSION OF U.S. FEDERAL TAX CONSIDERATIONS IS FOR GENERAL INFORMATION PURPOSES ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, GIFT, ESTATE, STATE, LOCAL, AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

UNDERWRITING

BofA Securities, Inc., Jefferies LLC and Raymond James & Associates, Inc. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

<u>Underwriter</u>	<u>Number of Shares</u>
BofA Securities, Inc.	
Jefferies LLC	
Raymond James & Associates, Inc.	
LifeSci Capital LLC	
Ladenburg Thalmann & Co. Inc.	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ _____ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	<u>Per Share</u>	<u>Without Option</u>	<u>With Option</u>
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The expenses of the offering, not including the underwriting discount, are estimated at \$ _____ and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to \$ _____.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Jefferies LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock,
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise, or
- publicly disclose the intention to do any of the foregoing.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. BofA Securities, Inc. and Jefferies LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice. In addition, in the event that one or more stockholders is granted an early release from any restriction on transfer described in the lock-up agreements during the lockup period described therein with respect to our securities in an aggregate amount in excess one percent of our issued and outstanding shares of common stock on an as-converted to common stock basis (whether in one or multiple releases), then each stockholder holding in excess of percent of the outstanding shares of our securities on an as-converted to common stock basis, or a Major Holder, will automatically be granted an early release on the same terms from the lock-up restrictions on transfer under the lock-up agreement on a pro-rata basis. In the event of an underwritten primary or secondary public offering or sale of our common stock during the period ending 180 days after the date of this prospectus, such early release shall only apply with respect to such Major Holder's participation in such offering.

Nasdaq Global Market Listing

We expect the shares to be approved for listing on the Nasdaq Global Market, subject to notice of issuance, under the symbol "TARS."

[Table of Contents](#)

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are

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

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

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a

Table of Contents

decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area and the United Kingdom

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

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

provided that no such offer of shares shall require the Company or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Table of Contents

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the representatives that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

The Company, the underwriters and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

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

References to the Prospectus Regulation includes, in relation to the UK, the Prospectus Regulation as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018.

The above selling restriction is in addition to any other selling restrictions set out below.

In connection with the offering, the underwriters are not acting for anyone other than the Company and will not be responsible to anyone other than the Company for providing the protections afforded to their clients nor for providing advice in relation to the offering.

Notice to Prospective Investors in the United Kingdom

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the “Financial Promotion Order”), (ii) are persons falling within Article 49(2)(a) to (d) (“high net worth companies, unincorporated associations etc.”) of the Financial Promotion Order, (iii) are outside the United Kingdom or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as “relevant persons”). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

[Table of Contents](#)

Neither this document nor any other offering or marketing material relating to the offering, the Company, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors, who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which

Table of Contents

do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA,) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- (c) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (d) where no consideration is or will be given for the transfer;

Table of Contents

- (e) where the transfer is by operation of law; or
- (f) as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

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

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (**NI 33-105**), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of our common stock offered in this prospectus will be passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, San Diego, California. Shearman & Sterling LLP, New York, New York is acting as counsel for the underwriters in connection with this offering. Certain investment partnerships comprised of partners of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, own an interest representing less than one percent of the shares of our common stock.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2018 and 2019, and for each of the two years in the period ended December 31, 2019, as set forth in their report. We've included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits, schedules and amendments to the registration statement. Please refer to the registration statement and to the exhibits and schedules for further information with respect to the common stock offered by this prospectus. Statements contained in this prospectus regarding the contents of any contract, agreement or other document are only summaries. With respect to any contract, agreement or document that is filed as an exhibit to the registration statement, you should refer to the exhibit for a copy of the contract, agreement or document, and each statement in this prospectus regarding that contract, agreement or document is qualified by reference to the exhibit. The SEC maintains an Internet website that contains the registration statement of which this prospectus forms a part, as well as the exhibits thereto. These documents, along with future reports, proxy statements and other information about us, are available at the SEC's website, www.sec.gov. The information on the SEC's web site is not part of this prospectus, and any references to this web site or any other web site are inactive textual references only.

Upon completion of this offering, we will become subject to the information and reporting requirements of the Exchange Act, and, in accordance with this law, will be required to file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available on the SEC's website referred to above. We also maintain a website at www.tarsusrx.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not a part of this prospectus. Investors should not rely on any such information in deciding whether to purchase our common stock. We have included our website address in this prospectus solely as an inactive textual reference.

[Table of Contents](#)

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

	<u>Pages</u>
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations and Comprehensive Loss	F-4
Statements of Preferred Stock and Stockholders' Deficit	F-5
Statements of Cash Flows	F-6
Notes to Financial Statements	F-7

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, 2018 and 2019, the related statements of operations and comprehensive loss, preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2019, and the results of its operations and its cash flows for the years then ended 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 and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

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

Irvine, California
August 7, 2020

TARSUS PHARMACEUTICALS, INC.

BALANCE SHEETS

(In thousands, except share and par value amounts)

	December 31,	
	2018	2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,355	\$57,952
Restricted cash	20	20
Other receivables	4	36
Prepaid expenses	4	22
Total current assets	<u>2,383</u>	<u>58,030</u>
Property and equipment, net of accumulated depreciation	6	154
Operating lease right-of-use asset	—	126
Other assets	—	6
Total assets	<u>\$ 2,389</u>	<u>\$58,316</u>
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 176	\$ 520
Accrued payroll and benefits	3	299
Total current liabilities	<u>179</u>	<u>819</u>
Operating lease liability, non-current portion	—	100
Total liabilities	<u>179</u>	<u>919</u>
Commitments and contingencies (Note 10)		
Series A Preferred Stock, \$0.001 par value; 12,820,512 and 11,698,716 shares authorized at December 31, 2018 and 2019, respectively; 11,698,716 shares issued and outstanding at December 31, 2018 and 2019; liquidation preference of \$3,650 at December 31, 2018 and 2019	3,564	3,564
Series B Preferred Stock, \$0.001 par value; zero shares authorized, issued or outstanding at December 31, 2018 and 50,000,000 shares authorized and 49,578,623 shares issued and outstanding at December 31, 2019; liquidation preference of \$0 and \$60,010 at December 31, 2018 and 2019, respectively	—	59,838
Stockholders' deficit:		
Common stock, \$0.0001 par value; 103,000,000 shares authorized; 19,890,000 shares issued and 15,441,387 outstanding excluding 4,448,613 shares subject to repurchase at December 31, 2018; 19,690,000 shares issued and 19,658,055 outstanding excluding 31,945 shares subject to repurchase at December 31, 2019	1	2
Additional paid-in capital	9	27
Accumulated deficit	<u>(1,364)</u>	<u>(6,034)</u>
Total stockholders' deficit	<u>(1,354)</u>	<u>(6,005)</u>
Total liabilities, preferred stock and stockholders' deficit	<u>\$ 2,389</u>	<u>\$58,316</u>

See accompanying notes to these financial statements.

TARSUS PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2018	2019
Operating expenses:		
Research and development	\$ 901	\$ 3,162
General and administrative	449	1,136
Total operating expenses	1,350	4,298
Loss from operations before other income (expense) and income taxes	(1,350)	(4,298)
Other income (expense):		
Interest income (expense), net	32	(40)
Loss on extinguishment of convertible notes	—	(255)
Change in fair value of derivative liabilities	—	(76)
Total other income (expense)	32	(371)
Provision for income taxes	(1)	(1)
Net loss and comprehensive loss	\$ (1,319)	\$ (4,670)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.10)	\$ (0.26)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	13,068,854	17,728,991
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		\$ (0.15)
Weighted-average shares outstanding used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		32,008,512

See accompanying notes to these financial statements.

TARSUS PHARMACEUTICALS, INC.

STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2017	—	\$ —	10,651,388	\$ 1	\$ —	\$ (45)	\$ (44)
Net loss	—	—	—	—	—	(1,319)	(1,319)
Recognition of stock-based compensation expense	—	—	—	—	9	—	9
Issuance of common stock under stock purchase agreements	—	—	40,000	—	—	—	—
Vesting of founder shares subject to repurchase	—	—	4,000,000	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	749,999	—	—	—	—
Issuance of Series A Preferred Stock for cash, net of issuance costs of \$86	11,698,716	3,564	—	—	—	—	—
Balance as of December 31, 2018	11,698,716	\$ 3,564	15,441,387	\$ 1	\$ 9	\$ (1,364)	\$ (1,354)
Net loss	—	—	—	—	—	(4,670)	(4,670)
Recognition of stock-based compensation expense	—	—	—	—	18	—	18
Vesting of founder shares subject to repurchase	—	—	3,666,667	1	—	—	1
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	550,001	—	—	—	—
Issuance of Series B Preferred Stock upon conversion of Convertible Notes	1,991,052	2,410	—	—	—	—	—
Issuance of Series B Preferred Stock for cash, net of issuance costs of \$172	47,587,571	57,428	—	—	—	—	—
Balance as of December 31, 2019	<u>61,277,339</u>	<u>\$ 63,402</u>	<u>19,658,055</u>	<u>\$ 2</u>	<u>\$ 27</u>	<u>\$ (6,034)</u>	<u>\$ (6,005)</u>

See accompanying notes to these financial statements.

TARSUS PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS
(In thousands)

	<u>Year ended December 31,</u>	
	<u>2018</u>	<u>2019</u>
Cash Flows From Operating Activities:		
Net loss	\$ (1,319)	\$ (4,670)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1	37
Stock-based compensation (<i>Note 5</i>)	9	18
Amortization of operating lease right-of-use asset (<i>Note 10(a)</i>)	—	37
Change in fair value of derivative liabilities (<i>Note 9</i>)	—	76
Non-cash related party interest expense	—	89
Loss on extinguishment of convertible notes (<i>Note 9</i>)	—	255
Changes in operating assets and liabilities:		
Other receivables	(4)	(32)
Prepaid expenses	(4)	(18)
Other non-current assets	—	(6)
Accounts payable and other accrued liabilities	131	245
Accrued payroll and benefits	3	296
Net cash used in operating activities	<u>(1,183)</u>	<u>(3,673)</u>
Cash Flows From Investing Activities:		
Purchases of property and equipment	(7)	(175)
Cash used in investing activities	<u>(7)</u>	<u>(175)</u>
Cash Flows From Financing Activities:		
Proceeds from issuance of Series A Preferred Stock, net of issuance costs (<i>Note 4</i>)	3,564	—
Proceeds from issuance of Series B Preferred Stock, net of issuance costs (<i>Note 4</i>)	—	57,456
Proceeds from issuance of convertible notes, net of issuance costs (<i>Note 9</i>)	—	1,989
Net cash provided by financing activities	<u>3,564</u>	<u>59,445</u>
Net increase in cash, cash equivalents and restricted cash	<u>2,374</u>	<u>55,597</u>
Cash, cash equivalents, and restricted cash — beginning of year	<u>1</u>	<u>2,375</u>
Cash, cash equivalents, and restricted cash — end of year	<u>2,375</u>	<u>57,972</u>
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	\$ 2,355	\$ 57,952
Restricted cash	20	20
Cash, cash equivalents and restricted cash	<u>\$ 2,375</u>	<u>\$ 57,972</u>
Supplemental Disclosures Noncash Investing and Financing Activities:		
Operating lease right-of-use asset obtained in exchange for operating lease liability	\$ —	\$ 163
Settlement of derivative liabilities upon conversion of convertible notes (<i>Note 9</i>)	\$ —	\$ 363
Additions of property and equipment in accounts payable and other accrued liabilities (<i>Note 3(b)</i>)	\$ —	\$ 10
Series B Preferred Stock issuance costs in accounts payable and other accrued liabilities	\$ —	\$ 28
Conversion of convertible notes to Series B Preferred Stock (<i>Note 9</i>)	\$ —	\$ 2,410

See accompanying notes to these 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

(a) Description of Business

Tarsus Pharmaceuticals, Inc. (“Tarsus” or the “Company”) is a late clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutic candidates to address large market opportunities initially in ophthalmic conditions where there are limited treatment alternatives.

(b) Risks and Liquidity

The Company has no revenue and incurred losses and negative cash flows from operations since inception, resulting in an accumulated deficit of \$6.0 million as of December 31, 2019. The Company’s cash and cash equivalents was \$2.4 million and \$58.0 million as of December 31, 2018 and 2019, respectively, and has historically financed its operations primarily through equity capital raises. The Company believes that existing capital resources will be sufficient to meet projected operating requirements for at least 12 months from the date of issuance of the accompanying financial statements, though expects to incur operating losses for the foreseeable future.

The Company’s operations have consisted primarily of its organization, securing financing, in-licensing intellectual property, and conducting preclinical and clinical studies. The Company faces risks associated with early-stage biotechnology companies whose product candidates are in development that require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require the Company to expend large amounts of additional capital to complete research and development, achieve research and development objectives, defend intellectual property rights, and recruit and retain skilled personnel, including key members of management.

If the Company raises additional funds by issuing equity securities, its stockholders may experience dilution. Any future debt financing into which the Company enters may impose additional covenants that restrict operations, including limitations on its ability to incur liens or additional debt, pay dividends, repurchase common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity raise may contain terms that are not favorable to the Company or its stockholders. Further, adequate funding may not be available on acceptable terms, or at all. The Company’s potential inability to raise capital when needed could have a negative impact on its financial condition and ability to pursue planned business strategies. If the Company is unable to raise additional funds as required, it may need to delay, reduce, or terminate some or all 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. If the Company is required to enter into collaborations and other arrangements to address its liquidity needs, it may have to give up certain rights that limit its ability to develop and commercialize product candidates or may have other terms that are not favorable to the Company or its stockholders, which could materially and adversely affect its business and financial prospects.

(c) Operating Segment

To date, the Company has operated and managed its business and financial information on an aggregate basis for the purposes of evaluating financial performance and the allocation of resources. Accordingly, the Company’s management determined that it operates in one reportable operating segment that is focused exclusively on developing pharmaceutical products.

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

(d) Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or 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 and, as a result, 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

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (“GAAP”) and with the rules and regulations of the Securities and Exchange Commission (“SEC”) requires management to make informed estimates and assumptions that affect the amounts reported in these financial statements and accompanying notes. These amounts may materially differ from the amounts ultimately realized and reported due to the inherent uncertainty of any estimate or assumption. On an on-going basis, management evaluates its most critical estimates and assumptions, including those related to the (i) fair value of stock awards and periodic expense recognition of stock-based compensation, (ii) the realization of income tax assets and estimates of tax liabilities, (iii) expense accruals related to research and development activities, including clinical trials, and (iv) valuation of convertible notes, derivative instruments, and preferred stock.

Accounting policies and estimates that most significantly impact the presented amounts within these financial statements are further described below:

(i) Cash and Cash Equivalents

Cash and cash equivalents consist of bank deposits and highly liquid investments, including money market fund accounts, with original maturities of three months or less from the purchase date.

(ii) Restricted Cash

Restricted cash represents cash held as collateral for the Company’s corporate credit card program. Any cash that is legally or contractually restricted from immediate use is classified as restricted cash.

In November 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* (“ASU 2016-18”), which requires companies to include restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company early adopted ASU 2016-18 on January 1, 2018, as reflected in the accompanying Statements of Cash Flows.

(iii) 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 and cash equivalents in deposits at financial institutions that are in excess of federally insured limits.

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

In March 2020, the World Health Organization declared a pandemic related to the global novel coronavirus disease 2019 (“COVID-19”) outbreak. The Company’s operations have not been significantly impacted by the COVID-19 pandemic. The Company has been carefully monitoring the potential impact COVID-19 may have on the Company’s business. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its financial condition and operations, including ongoing and planned clinical trials.

The Company’s results of operations involve numerous risks and uncertainties. Factors that could affect the Company’s operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials, uncertainty of regulatory approval of the Company’s potential product candidates, including TP-03 for ophthalmic conditions and TP-04 for treatment of skin conditions, uncertainty of market acceptance of its product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers.

The Company’s product candidates require approvals from the U.S. Food and Drug Administration (“FDA”) and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval for any product candidate, it could have a materially adverse impact on the business.

(iv) Property and Equipment

Property and equipment is stated at historical cost and is depreciated on a straight-line basis over an estimated useful life that corresponds with its designated asset category. 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 “long-lived assets” (which includes property and equipment) whenever events or changes in circumstances in 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 events or changes in business circumstances during the years ended December 31, 2018 and 2019 that indicated the carrying amounts of any long-lived assets were not fully recoverable.

(v) Derivative Instruments

The convertible notes issued in May 2019, August 2019, and October 2019 contained embedded derivative instruments, representing “contingent redemption options”. The contingent redemption options met the requirements for separate accounting and were accounted for as a single derivative instrument for each tranche of the convertible notes. The derivative instruments were recorded at fair value at inception and were subject to remeasurement to fair value, with any changes in estimated fair value recognized as a component of “other (expense) income” in the Statements of Operations (see *Note 8*).

(vi) 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. These expenses also

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

include internal costs directly attributable to in-development programs, including cost of certain salaries, payroll taxes, employee benefits, and stock-based compensation expense, as well as laboratory and clinical supplies, pre-clinical and clinical trial related expenses, and the cost of services provided by outside contractors. Prior to receiving invoices from its vendors, the Company accrues expense for pre-clinical studies and clinical trial activities performed by these third parties. This is typically based upon estimates of the proportion of work completed over the term of the individual study or trial, as well as patient enrollment and dosing events in accordance with agreements established with clinical research organizations (CROs) and clinical trial or pre-clinical study sites.

The Company has entered, and may continue to enter into, license agreements to access and utilize intellectual property for drug development. In each case, the Company evaluates if the assets acquired in a transaction represent the acquisition of an asset or a business, as defined under applicable GAAP. The Company's only executed in-license agreement (see *Note 10(b)*) was evaluated and determined to represent an asset acquisition. Because this asset had not yet received regulatory approval and has no alternative future use, its fair value was immediately recognized as research and development expense. In addition, any future milestone payments made before product approval (that do not meet the definition of a derivative) will also be immediately recognized as research and development expense when paid or becomes payable, provided there is no alternative future use of the rights in other research and development projects.

(vii) Stock-Based Compensation

Stock-based compensation expense is recognized for all equity awards granted to employees, consultants, and members of the Company's Board of Directors and is recognized at fair value. For stock-based awards that vest subject to the satisfaction of a service requirement, the fair value measurement date is the date of grant and 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 compensation cost if and when it concludes that it is probable that the performance condition will be achieved and the related expense is recognized on an accelerated attribution method. As applicable, the Company reverses previously recognized expense for forfeitures of unvested awards in the period of occurrence. The Company uses the Black-Scholes option pricing model to estimate the fair value of stock-based awards as of the date of grant.

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 the Company's common stock on the date of the option grant, (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 as the Company does not yet have sufficient exercise history since its November 2016 formation. Further, the Company is privately-held and therefore lacks company-specific historical and implied volatility information of its stock. Accordingly, management estimates this expected volatility using that of its 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. 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 time periods that correspond 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.

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

Given the absence of a public trading market, the Company's 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 the Company's common stock; (ii) the Company's stage of development; (iii) the status of research and development efforts; (iv) the rights, preferences and privileges of the Company's preferred stock relative to common stock; (v) the Company's operating results and financial condition, including the Company's 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 the Company's common stock.

(viii) 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. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. 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.

In the event that the Company is assessed interest and/or penalties from taxing authorities that have not been previously accrued, such amounts would be included as a component of "income tax expense" within the Statements of Operations in the period the notice was received. To date there have been no interest or penalties charged.

(ix) Preferred Stock

The Company classifies preferred stock outside of stockholders' deficit on the accompanying balance sheets. The requirements of a deemed liquidation event, as defined within its amended and restated certificate of incorporation filed in 2019 (the "2019 Amended and Restated Certificate of Incorporation") are not entirely within the Company's control. In the event of such a deemed liquidation event, the proceeds from the event are distributed in accordance with the liquidation preferences, provided that the holders of preferred stock have not converted their shares into common stock. The Company records the issuance of preferred stock at the issuance price less related issuance costs. The Company has not adjusted the carrying value of outstanding preferred stock to its liquidation preference because a deemed liquidation event is not probable of occurring as of the end of the reporting period.

(x) Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without the consideration for

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

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 share equivalents outstanding for the period determined using the treasury-stock method and if-converted method, as applicable. Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. The Company's participating securities include preferred stock, unvested common stock to founders, and unvested common stock awards issued upon early exercise of certain stock options. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Shares of common stock subject to repurchase by the Company are excluded from the weighted-average shares. Due to net losses in all periods presented, all otherwise potentially dilutive securities are antidilutive. Accordingly, basic net loss per share equals diluted net loss per share for all period presented in the accompanying financial statements.

(xi) Unaudited Pro forma Net Loss Per Share Attributable to Common Stockholders

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders has been computed to give effect to the automatic conversion of all outstanding preferred stock into shares of common stock using the if-converted method immediately prior to the closing of a qualifying initial public offering ("IPO") (*Note 4*) as though such IPO had occurred as of the beginning of the period or the date of issuance, if later. The unaudited pro forma net loss per share does not include the shares expected to be sold and related proceeds to be received from the IPO of Tarsus' common stock.

(xii) 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 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 and cash equivalents, accounts payable and accrued liabilities approximate fair value due to their short maturities. Derivative instruments are carried at fair value based on unobservable market inputs.

(xiii) Comprehensive Loss

Comprehensive loss represents all changes in stockholders' deficit, except those resulting from distributions to stockholders. For all periods presented, comprehensive loss was the same as reported net loss.

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

(xiv) 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 and expected future financial position, results of operations, or cash flows.

3. BALANCE SHEET ACCOUNT DETAIL

The composition of selected financial statement captions that comprise the accompanying balance sheets are summarized below:

(a) Property and Equipment, net of Accumulated Depreciation

"Property and equipment, net of accumulated depreciation" consists of the following:

	December 31,	
	2018	2019
Furniture and fixtures	\$ 1	\$ 5
Office equipment	—	26
Lab equipment	6	92
Leasehold improvements	—	69
Property and equipment, at cost	7	192
(Less): Accumulated depreciation	1	38
Property and equipment, net of accumulated depreciation	<u>\$ 6</u>	<u>\$154</u>

Depreciation expense (included within "total operating expenses" in the accompanying Statements of Operations) for the years ended December 31, 2018 and 2019 was \$1 thousand and \$37 thousand, respectively.

(b) Accounts Payable and Other Accrued Liabilities

"Accounts payable and other accrued liabilities" consists of the following:

	December 31,	
	2018	2019
Trade accounts payable	\$175	\$456
Shares subject to repurchase from its founders (Note 5)	1	—
Operating lease liability, current portion	—	64
Accounts payable and other accrued liabilities	<u>\$176</u>	<u>\$520</u>

4. STOCKHOLDERS' EQUITY*Authorized Stock*

Under the December 2019 Amended and Restated Certificate of Incorporation, the Company is authorized to issue two classes of stock: common and preferred. The total number of shares authorized for

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

issuance is 103 million of common shares and 61.7 million of preferred shares, of which 11.7 million shares are designated as Series A Preferred Stock and 50 million shares are designated as Series B Preferred Stock.

*Preferred Stock Overview**Series A Preferred Stock Issuance*

In March and May 2018, the Company executed a private placement Series A Stock Purchase Agreement and issued 11.7 million shares of Series A Preferred Stock at \$0.312 per share for net proceeds of \$3.6 million, after issuance costs of \$0.1 million.

<u>As of December 31, 2018</u>	<u>Authorized</u>	<u>Outstanding</u>	<u>Net Carrying Value</u>	<u>Liquidation Preference</u>	<u>Original Issue Price</u>
Series A Preferred Stock	12,820,512	11,698,716	\$ 3,564	\$ 3,650	\$ 0.312

Series B Preferred Stock Issuance

In December 2019, the Company executed a private placement Series B Stock Purchase Agreement of 47.6 million shares of Series B Preferred Stock at \$1.2104 per share for net proceeds of \$57.4 million, after issuance costs of \$0.2 million. Concurrently, convertible notes issued in May, August, and October 2019 for aggregate proceeds of \$2.0 million were converted based on principal and accrued interest, and the Company issued 2.0 million shares of Series B Preferred Stock at its contractual conversion price (see *Note 9*).

<u>As of December 31, 2019</u>	<u>Authorized</u>	<u>Outstanding</u>	<u>Net Carrying Value</u>	<u>Liquidation Preference</u>	<u>Original Issue Price</u>
Series A Preferred Stock	11,698,716	11,698,716	\$ 3,564	\$ 3,650	\$ 0.312
Series B Preferred Stock	50,000,000	49,578,623	\$ 59,838	\$ 60,010	\$ 1.2104
Total	61,698,716	61,277,339	\$ 63,402	\$ 63,660	

*Significant Provisions of Series A and Series B Preferred Stock**Conversion Rights and Mandatory Conversion*

Each share of Series A and Series B Preferred Stock is convertible into common shares determined by dividing the original issuance price by the conversion price and at the sole option of the holder on a one-to-one basis. The conversion price will be adjusted for stock splits, distributions, dividends, noncash distributions, share purchase rights, and capital reorganizations. In addition, subject to customary exceptions, the conversion price for each series of preferred stock will be reduced upon the issuance or sale of common shares or instruments convertible or exercisable into common shares, for consideration or with an exercise price that is less than the conversion price applicable to such series. Such reduction may result in recognition of a deemed dividend to preferred stockholders if the resulting conversion price is less than the fair value per share of common stock as of the date preferred stock was issued.

Mandatory conversion into common shares will occur upon either (i) the closing of a Qualified Public Offering, which is defined in the December 2019 Amended and Restated Certificate of Incorporation to include the sale of common stock in a firm commitment underwritten public offering on Form S-1, the public offering

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

price of which is at least \$3.03 per share and that results in at least \$60 million of proceeds, or (ii) by vote or written consent or agreement of the holders of a majority of the then-outstanding shares of Series A and Series B Preferred Stock, voting together as a single class on an as-converted basis.

Liquidation Preference

In the event of any Liquidation Event (as defined in the December 2019 Amended and Restated Certificate of Incorporation), the holders of Series A and B Preferred Stock are first entitled to proceeds or assets available for distribution that are in preference of any distribution to common stockholders (the "Liquidation Preference"); provided, however, that if the holders of Series A and Series B Preferred Stock would receive greater proceeds in a Liquidation Event as a result of their conversion to common stock such shares of Series A and/or Series B Preferred Stock shall be deemed to have automatically thus converted. This Liquidation Preference is equal to the *sum of* (i) the original issue price of Series A and Series B Preferred Stock (\$0.312 and \$1.2104 per share, respectively) for each outstanding share of Series A and Series B Preferred Stock and (ii) any declared but unpaid dividends for each outstanding share of Series A and Series B Preferred Stock. If the proceeds from the Liquidation Event are less than the Liquidation Preference, then all available proceeds will be distributed ratably to the holders of Series A and Series B Preferred Stock in proportion to the preferential amount each is otherwise entitled to receive. After the distributions described above have been paid in full, the remaining assets of the Company will be distributed among the holders of common stock pro rata based on the number of shares held by each holder.

Voting Rights

The holder of each share of preferred stock has the right to one vote for each share of common stock into which such preferred stock could then be converted, and with respect to such vote, such holder has full voting rights and powers equal to the voting rights and powers of the holders of common stock. So long as the majority of the Series A Preferred Stock originally issued remains outstanding, its holders are additionally entitled to elect one director ("Series A Director"). So long as at least 10 million shares of Series B Preferred Stock remain outstanding, its holders are entitled to elect two directors (each a "Series B Director"). The holders of outstanding common stock are entitled to elect three directors. The holders of preferred stock and common stock (voting together as a single class and on an as-converted basis) are entitled to elect any of the Company's remaining directors.

Dividend Rights

The holders of Preferred Stock are entitled to receive dividends, when, as and if declared by the Board of Directors at the applicable dividend rate set forth in the December 2019 Amended and Restated Certificate of Incorporation (\$0.03 and \$0.10 per annum for each share of Series A and Series B Preferred Stock, respectively), prior and in preference to any declaration or payment of any cash dividend on the common stock. The Company cannot declare, pay, or set aside any dividends on shares of any class or series of capital stock unless the Series A and Series B Preferred Stockholders first receive a dividend in an amount equal to the greater of (i) applicable dividend rate, or (ii) the dividend payable to such other class or series of capital stock. No cash dividends have been declared to date.

Redemption Rights

The Series A and Series B Preferred Stock are not redeemable at the option of its holder under the terms of the December 2019 Amended and Restated Certificate of Incorporation. Upon certain change in control events

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

that are outside of the Company's control, including its liquidation, sale or transfer of control, the preferred stock is contingently redeemable.

Common Stock Overview and Reserve for Future Issuance

Common stockholders have one vote for each share of common stock held and are entitled to receive any dividends declared by the Company's Board of Directors when legally available for distribution, subject to the dividend rights of the holders of Series A and Series B preferred stock discussed above. For the years ended December 31, 2018 and 2019, no dividends were declared.

As of December 31, 2018 and 2019, the Company had 19.9 million and 19.7 million common shares issued, respectively. At December 31, 2018 and 2019, the Company had 12.4 million and 15.7 million common shares outstanding, respectively. The following shares of common stock were reserved for issuance:

	December 31,	
	2018	2019
Preferred Stock outstanding	11,698,716	61,277,339
Stock options issued and outstanding under the 2016 Plan	1,983,543	2,207,154
Stock options available for future grant under the 2016 Plan	563,457	15,975,661
Total shares of common stock reserved	14,245,716	79,460,154

Adoption of ASU 2017-11

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. This ASU simplifies the accounting for certain financial instruments with "down round" features, a provision in an equity-linked financial instrument (or embedded feature) that provides a downward adjustment of the current exercise price based on the price of future equity offerings. This update requires companies to disregard the down round feature when assessing whether the instrument is "indexed to its own stock" for purposes of determining liability or equity classification. For public business entities, this ASU became effective for fiscal years beginning after December 15, 2018. The Company adopted *ASU 2017-11* effective January 1, 2019 and applied this guidance in presenting Series A and Series B Preferred Stock on the accompanying Balance Sheets.

5. STOCK-BASED COMPENSATION***2016 Stock Plan***

The Company has one active stockholder-approved stock-based compensation plan (the "2016 Plan"), adopted in December 2016, which permits the grant of incentive stock options, nonqualified stock options, stock awards and certain other awards to its employees, members of its Board of Directors, and consultants.

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

The stated maximum availability of common stock under the 2016 Plan is 19.8 million shares. As of December 31, 2019, the Company had 16.0 million shares of common stock available for issuance under the 2016 Plan.

Stock-based awards are governed by agreements between the Company and the recipients. Incentive stock options and nonqualified stock options may be granted under the 2016 Plan at an exercise price of not less than 100% of the fair market value of common stock on the respective date of grant. For ten-percent stockholders, the exercise price may not be less than 110% of its fair market value at grant. The grant date is the date the terms of the award are formally approved by the Company's Board of Directors. It is the Company's policy that before stock is issued through the exercise of stock options, it must first receive all required cash proceeds for such shares.

Through December 31, 2019, all awards issued under the 2016 Plan were in the form of stock options. These option agreements have service and/or performance conditions for vesting, unless immediately vested on the date of grant. Stock options granted typically have one to four-year service conditions for full vesting. The performance conditions for vesting are explicitly stated in each option agreement and are associated with clinical, business development, or operational milestones.

Stock options must generally be exercised, if at all, no later than 10 years from the date of grant. Upon termination of employment, vested stock options may be exercised within 12 months after the date of termination upon death; six months after the date of termination upon disability; and three months after the date of termination for all other separations.

Adoption of ASU 2018-07

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This standard is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share-based payments. The ASU expands the scope of *Topic 718* to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees is substantially aligned; the Company has issued and outstanding stock options to both employees and non-employee consultants. The standard is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted, but no earlier than a company's adoption date of *Topic 606, Revenue Recognition*. The Company early adopted *ASU 2018-17* and *Topic 606* on January 1, 2018 and there was no material impact on the accompanying financial statements from these adopted standards.

Stock-Based Compensation Summary

Stock-based compensation expense is recorded in the accompanying statements of operations based on the assigned department of the award recipient. Stock-based compensation expense for the years ended December 31, 2018 and 2019 was as follows:

	Year Ended December 31,	
	2018	2019
Research and development	\$ 3	\$ 6
General and administrative	6	12
Total stock-based compensation	<u>\$ 9</u>	<u>\$ 18</u>

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

Valuation Assumptions of Stock Options

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,	
	2018	2019
Exercise price (estimated fair value per common share on grant date)	\$ 0.06	\$ 0.06
Expected term (in years) (a)	5.68 to 6.25	5.94 to 6.25
Risk-free interest rate (b)	2.9%	2.4% to 2.5%
Expected volatility (c)	77.8% to 83.2%	82.5% to 89.4%
Expected dividend yield (d)	—	—
Weighted-average grant-date fair value per stock option	\$ 0.05	\$ 0.05

- (a) Determined using the “simplified method” under applicable GAAP (*SAB 107*); the maximum contractual term of issued stock options is 10 years.
- (b) Based upon the U.S. Treasury yields in effect during the period which the options were granted (for a period equaling the stock options’ expected term).
- (c) Measured using the volatility of the stock price for the Company’s designated peer group of publicly-traded companies for a period equal to the expected option term.
- (d) Tarsus does not expect to declare any cash dividends in the foreseeable future.

Stock Option Activity

Stock option activity during the years ended December 31, 2018 and 2019 was as follows:

	Number of Shares	Weighted- Average Exercise Price/Share	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding — December 31, 2017	622,500	\$ 0.0001	9.91	\$ —
Granted	1,361,043	0.06		
Exercised	—			
Forfeited	—			
Expired	—			
Outstanding — December 31, 2018	1,983,543	0.04	9.51	\$ 37
Granted	243,611	0.06		
Exercised	—			
Forfeited	(14,167)	0.06		
Expired	(5,833)	0.06		
Outstanding — December 31, 2019	2,207,154	\$ 0.04	8.60	\$ 37(1)
Vested — December 31, 2019	935,207	\$ 0.03	8.38	\$ 26(1)
Unvested — December 31, 2019	1,271,947	\$ 0.05	8.76	\$ 11(1)

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) Represents the total *difference* between the estimated stock price fair value as of December 31, 2019 and the stock option exercise price, *multiplied* by the number of in-the-money options as of December 31, 2019. 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, 2018 and 2019 was \$33 thousand in each year.

The following table summarizes information with respect to stock option grants as of December 31, 2019:

Exercise Price	As of December 31, 2019					
	Outstanding			Exercisable		
	Granted Stock Options Outstanding	Aggregate Intrinsic Value	Weighted-Average Remaining Contractual Life (Years)	Granted Stock Options Exercisable	Aggregate Intrinsic Value	Weighted-Average Remaining Contractual Life (Years)
\$0.0001	622,500	\$ 37	7.91	622,500	\$ 37	7.91
\$0.06	1,584,654	—	8.87	1,089,624	—	8.80
	<u>2,207,154</u>	<u>\$ 37</u>	<u>8.60</u>	<u>1,712,124</u>	<u>\$ 37</u>	<u>8.48</u>

As of December 31, 2019, there was unrecognized compensation expense of \$46 thousand related to unvested stock options, which the Company expects to recognize over a weighted average period of 2.1 years.

Early Exercise Feature of Certain Stock Options

The 2016 Plan permits certain option holders to exercise awarded options prior to vesting. Upon early exercise, the options become subject to a restricted stock agreement and remain subject to the same vesting provisions in the corresponding stock option award and unvested options are subject to repurchase by the Company upon termination at the same price exercised. These unvested shares are reported as issued, but not outstanding while subject to repurchase by the Company and are also excluded from the basic and diluted net loss per share calculation until the repurchase right lapses upon vesting.

The Company initially records a liability for these early exercises that is subsequently reclassified into stockholders' equity on a pro rata basis as vesting occurs. During the year ended December 31, 2019, the Company repurchased 200,000 of unvested common stock options from a former consultant in connection with termination of his consulting agreement; there were no such repurchases in 2018. As of December 31, 2018 and 2019, all stock options with early exercise features were either vested or immaterial if early exercised and the Company reported no corresponding liability in the accompanying Balance Sheets.

Restricted Stock Issued to Founders

In January 2017, the Company issued 18 million shares of restricted common stock to founders, all which vest under service conditions. The shares were issued under the terms of the respective Stock Purchase Agreement. Unvested shares are subject to repurchase by the Company at the original purchase price per share upon the holder's termination of the relationship with the Company. The restricted shares are not deemed to be outstanding for accounting purposes until vested and are therefore excluded from reported shares outstanding and from the basic and diluted net loss per share calculation until the repurchase right lapses and are no longer

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

subject to the repurchase feature. One-third of the 18 million shares of restricted common stock were vested on the issuance date and the remaining 12 million shares vest monthly thereafter. During the years ended December 31, 2018 and 2019, 4.0 million and 3.7 million shares of restricted common stock, vested, respectively. As of December 31, 2019, no shares of this restricted stock issuance remain unvested.

6. NET LOSS PER SHARE

Net loss per share attributable to common stockholders was computed by dividing net loss by the weighted-average number of common shares outstanding for the years ended December 31, 2018 and 2019:

	Year Ended December 31,	
	2018	2019
Net loss	\$ (1,319)	\$ (4,670)
Weighted-average shares—basic and diluted	13,068,854	17,728,991
Net loss per share attributable to common stockholders— basic and diluted	\$ (0.10)	\$ (0.26)

The following outstanding potentially dilutive securities were excluded from the calculation of diluted net loss per share attributable to common stockholders because their impact under the “treasury stock method” and “if-converted method” would have been anti-dilutive for the periods presented:

	Year Ended December 31,	
	2018	2019
Stock options, unexercised - vested and unvested	1,983,543	2,207,154
Series A and Series B Preferred Stock, outstanding	8,974,357	14,279,521
Shares subject to repurchase from its founders	3,666,667	—
Stock options early-exercised and unvested	781,946	31,945
Convertible promissory notes	—	693,902
Total	15,406,513	17,212,522

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

7. UNAUDITED PRO FORMA NET LOSS PER SHARE

The following table sets forth the computation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2019:

	Year Ended December 31, 2019 <u>(unaudited)</u>
Numerator	
Net loss	\$ (4,670)
Denominator	
Weighted-average shares of common stock used in computing net loss per share attributable to common stockholders	17,728,991
Pro forma adjustment to reflect assumed conversion of Series A and Series B Preferred Stock (<i>Note 4</i>)	14,279,521
Weighted-average shares of common stock used in computing pro forma net loss per share attributable to common stockholders, basic and diluted	32,008,512
Pro forma net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.15)</u>

8. FAIR VALUE MEASUREMENTS

The table below summarizes certain financial instruments measured at fair value that are included within the accompanying balance sheets, and their designation among the three fair value measurement categories (see *Note 2(xi)*):

	Year Ended December 31, 2019 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	\$57,952	\$ —	\$ —	\$57,952
Total assets measured at fair value	<u>\$57,952</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$57,952</u>
	Year Ended December 31, 2018 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	\$ 2,355	\$ —	\$ —	\$ 2,355
Total assets measured at fair value	<u>\$ 2,355</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,355</u>

Money Market Funds

Money market fund holdings are included in cash and cash equivalents on the accompanying balance sheets and are classified within *Level 1* of the fair value hierarchy because of its readily-available market prices

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

in active markets that are publicly accessible at the measurement date. These money market funds are invested in U.S. Treasury, bills, notes, and other obligations issued or guaranteed as to principal and interest by the U.S. Government or its agencies.

Convertible Promissory Notes – Derivative Liabilities

The following table sets forth a summary of the changes in fair value of the bifurcated derivative liability associated with the convertible promissory notes issued and settled during 2019 to certain related parties (see *Note 9*). The measurement of the derivative liabilities represents a *Level 3* financial instrument:

	Derivative Liabilities
Fair value as of December 31, 2018	\$ —
Initial fair value of derivative liability upon issuance of May 2019 Notes	28
Initial fair value of derivative liability upon issuance of August 2019 Notes	50
Initial fair value of derivative liability upon issuance of October 2019 Notes	209
Revaluation of derivative liabilities included in other income (expense), net within the Statement of Operations for the year ended December 31, 2019	76
Settlement of derivative liabilities through conversion of all Notes	(363)
Fair value as of December 31, 2019	\$ —

The fair values of the derivative liabilities presented above were estimated at the date of issuance and at subsequent balance sheet dates using a two-step approach to valuation. Management utilized a probability-weighted valuation method and then compared the instrument's value with-and-without the derivative features in order to estimate their combined fair value, using unobservable inputs, which are classified as *Level 3* within the fair value hierarchy. The significant inputs not included in the market and thus represents a *Level 3* measurement in the valuation approach included the probability of achieving a settlement that provides the note holders the rights or the obligations to receive cash or a variable number of shares upon the completion of a then-future capital transaction. The convertible notes were issued and settled in full during the year ended December 31, 2019 (see *Note 9*).

9. CONVERTIBLE PROMISSORY NOTES PAYABLE**Overview of Notes and Conversion in December 2019**

In May 2019, the Company entered into a Note Purchase Agreement (the "May 2019 Purchase Agreement") with its co-founders and certain other related parties (the "Note Holders"). Under the terms of the May 2019 Purchase Agreement, the Company received cash proceeds of \$0.5 million and issued \$0.5 million of convertible promissory notes (the "May 2019 Notes") with a stated maturity of December 2020. These notes bore interest at a rate of 8.0% per annum, compounded annually, and payable at maturity. In the event of a qualified equity financing, the outstanding principal of the May 2019 Notes plus all accrued and previously unpaid interest would, at the option of the holder, either (i) automatically convert into shares of stock issued in the qualified

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

equity financing based on a conversion price equal to 90% of the issuance price paid by these new investors, or (ii) be repaid in full.

In August 2019, the Company amended and restated the May 2019 Purchase Agreement with the Note Holders and received an additional \$0.5 million of proceeds and issued new \$0.5 million convertible promissory notes to the same parties (the “August 2019 Notes”) with identical terms.

In October 2019, the Company entered into a new Note Purchase Agreement (the “October 2019 Purchase Agreement”) with the Note Holders. Under the terms of the October 2019 Purchase Agreement, the Company received proceeds of \$1.0 million and issued \$1.0 million of convertible promissory notes (the “October 2019 Notes,” collectively with the May 2019 Notes and the August 2019 Notes, the “Notes”) with a conversion price equal to 80% of the issuance price in a qualified equity financing.

In December 2019, the Company completed an issuance of Series B Preferred Stock (see *Note 5*). Upon this issuance, the \$2.0 million of Note principal value, along with accrued interest, were converted into 2.0 million shares of Series B Preferred Stock under its contractual terms. The Company recorded “loss on extinguishment of convertible notes” (non-cash) of \$0.3 million within “other income (expense)” in the accompanying Statements of Operations for the year ended December 31, 2019.

Embedded Derivative and its Accounting

The Notes allowed for redemption upon a qualified equity financing that was determined to be a contingent redemption feature that was not closely related to the Notes and was thus required to be bifurcated as a derivative liability on the balance sheet. Based on the features of this derivative, the Company accounted for it as an implied discount in presenting the carrying value of these Notes. This discount was accreted over the term to maturity of the Notes using the effective interest method, resulting in aggregate interest expense recognition (non-cash) of \$0.1 million for the year ended December 31, 2019.

Changes in the embedded derivatives’ fair value at each reporting period were recognized in the accompanying statement of operations within “changes in fair value of derivative liabilities,” resulting in incremental “other expense” recognition (non-cash) of \$0.1 million for the year ended December 31, 2019.

10. COMMITMENTS & CONTINGENCIES

(a) Facility Leases

Overview

In the ordinary course of business, the Company enters lease agreements with unaffiliated parties for the use of office and laboratory facilities and office equipment. As of December 31, 2019, the Company had one active facility lease in Irvine, California, that commenced on March 1, 2019 and expires April 30, 2022 (see *Note 12*). This lease has a renewal option at the end of term, for which the Company was not reasonably certain to exercise at the lease commencement. As such, the renewal option was not included in the lease term used to calculate the right-of-use lease asset and lease liability. Prior to March 1, 2019, the Company did not have any material lease arrangements.

The Irvine facility lease has minimum annual rent, payable monthly, and carries fixed annual rent increases. Under the arrangement, real estate taxes, certain operating expenses, and common area maintenance

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

are reimbursable to the lessor. These amounts are expensed as incurred, as they are variable in nature and therefore excluded from the measurement of the reported right-of-use asset and liability discussed below. During the years ended December 31, 2018 and 2019, the Company had no sublease arrangements with it as lessor.

Adoption of New Lease Standard, Topic 842

Beginning January 1, 2019, the Company adopted ASU 2016-02, *Leases* (“Topic 842”). Under this new lease accounting standard, the Company recognized a right-of-use asset and lease liability on the accompanying Balance Sheets for all material leases. Management elected the “modified retrospective approach” with an effective transition date of January 1, 2018 upon adoption and the available practical expedients. The Company also elected to (1) not separate “lease components” from “non-lease components” in the measurement of minimum payments for its leases and (2) not recognize a lease asset and liability for a term of 12 months or less. Lease expense is recognized on a straight-line basis over the expected term of the lease. In March 2019, the Company capitalized a right-of-use asset of \$0.2 million along with an accompanying \$0.2 million lease liability.

As part of applying Topic 842, the Company determines if an arrangement is or contains a lease and the classification of that lease at contract execution. The classification of leases as “operating” or “finance” leases along with the initial measurement and recognition of the associated right-of-use assets and lease liabilities is performed at the lease commencement date. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. Since an implicit rate for the operating lease for the Company’s Irvine facility was not determinable and was not implicit in the lease, the Company calculated an estimated incremental borrowing rate based upon what it would have to pay to borrow on a collateralized bases over a similar term and amount equal to the lease payments in a similar economic environment. The right-of-use lease asset is based on the corresponding lease liability and adjusted for (i) applicable payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives provided by the lessor.

Components of Lease Expense

The liability associated with each lease is amortized over the respective lease term using the effective interest rate method. The Company’s right-of-use asset is amortized over the lease term on a straight-line basis to lease expense, as reported on an allocated basis within “research and development” and “general and administrative” expenses on the accompanying Statements of Operations. For the year ended December 31, 2019, the Company recognized \$0.1 million for lease expense. There were no variable lease payments, including non-lease components such as common area maintenance fees, recognized as lease expense for the year ended December 31, 2019.

Weighted-Average Remaining Lease Term and Applied Discount Rate

The Company has one active lease as of December 31, 2019 for its Irvine office and laboratory facility, with a remaining lease term of two years and four months. The estimated incremental borrowing rate of 10% is utilized to present value future minimum lease payments since an implicit interest rate is not readily determinable in this lease.

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

Future Contractual Lease Payments as of December 31, 2019

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:

<u>Operating Leases - future payments</u>	<u>December 31,</u> <u>2019</u>
2020	\$ 77
2021	79
2022	27
2023	—
2024	—
Total future lease payments, undiscounted	\$ 183
(Less): Imputed interest	(19)
Present value of operating lease payments	<u>\$ 164</u>

(b) In-License Agreement for Lotilaner

In January 2019, the Company entered into a license agreement with Elanco Tiergesundheit AG (“Elanco”), granting the Company worldwide development and marketing rights (including sublicense rights) for lotilaner for the treatment or cure of any eye or skin disease or condition in humans (see *Note 12*) (the “Field”). Under this agreement, the Company has sole responsibility for development, regulatory, and commercialization activities for lotilaner in the Field.

The Company paid Elanco an upfront \$1.0 million at contract execution which is reported within “research and development” expense within the accompanying statements of operations for the year ended December 31, 2019. The Company agreed to make further payments to Elanco upon achievement of various clinical milestones for an aggregate maximum of \$6.0 million and various sales milestones for an aggregate maximum of \$79.0 million. In addition, the Company is obligated to pay contractual royalties to Elanco in the single digits of its future net sales. If the Company receives payments from sublicensees, it is obligated to pay Elanco a variable percentage in the low to mid double-digits of such proceeds, except for territories in which the Company achieved regulatory approval prior to sublicense execution.

(c) Employment Agreement

The Company entered into an employment agreement with its Chief Executive Officer in September 2018. This agreement provides for the payment of certain benefits upon his separation of employment under specified circumstances, such as in connection with a change in control event or other significant transaction.

(d) 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 has been or will be incurred.

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

(e) 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 varies, and in certain cases, is indefinite and does 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.

11. INCOME TAXES

A reconciliation of income taxes was computed by applying the statutory federal income tax rate in each period to the pretax loss for the years ended December 31, 2018 and 2019, and as adjusted for certain classes of transactions, as summarized below:

	Year Ended December 31,	
	2018	2019
Expected tax benefit at statutory rate	\$(277)	\$(981)
State income tax, net of federal benefit	(89)	1
Permanent items	13	4
Research and development credits	(56)	(31)
Loss on extinguishment of convertible notes	—	54
Non-deductible interest	—	35
Other	—	4
Change in valuation allowance	410	915
Income tax provision	<u>\$ 1</u>	<u>\$ 1</u>

Significant components of the deferred tax assets and liabilities at December 31, 2018 and 2019, are presented below:

	Year Ended December 31,	
	2018	2019
Deferred tax assets:		
Net operating loss carry forwards	\$ 348	\$ 961
Research and development credit carryforwards	57	88
Intangible assets	16	211
Other, net	3	104
Total deferred tax assets before valuation allowance	424	1,364
Less: valuation allowance	(424)	(1,338)
Total deferred tax assets	<u>\$ —</u>	<u>\$ 26</u>
Deferred tax liabilities, net:		
Operating lease right-of-use asset	—	(26)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

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

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 full 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 \$0.4 million and \$1.3 million at December 31, 2018 and 2019, respectively

At December 31, 2019, the Company has federal and California net operating loss carryforwards of approximately \$4.2 million and \$1.3 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 \$4.2 million includes \$45 thousand that will begin to expire in 2037 and \$4.1 million that will not expire but will only be able to be offset 80% of future taxable income within each year. The California net operating losses will begin to expire in 2037. At December 31, 2019, the Company had federal and California research and development tax credits of \$0.1 million each. The federal research and development tax credits begin to expire in 2037 unless previously utilized, and the California credit carryforwards are available indefinitely.

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.

The following table summarizes the changes to the gross unrecognized tax benefits for the years ended December 31, 2018 and 2019:

	Year Ended December 31,	
	2018	2019
Balance at beginning of year	\$—	\$ 20
Additions related to current year positions	20	13
Balance at end of year	<u>\$ 20</u>	<u>\$ 33</u>

The Company is subject to taxation in the United States and California. All tax years from inception are subject to examination by federal and state tax authorities. The Company's practice is to recognize interest and

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

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, 2018 and 2019 and the years then ended. Further, the Company is not currently under examination by any federal, state, or local tax authority.

12. SUBSEQUENT EVENTS

Subsequent events have been evaluated for recognition and measurement purposes through August 7, 2020, which is the date that the financial statements were available to be issued. Except as described below, the Company has concluded that no events or transactions have occurred that require disclosure.

New Office Leases

In May 2020, the Company entered two new facility leases in Irvine, California for expanded administrative and laboratory space. These adjacent suites each have commencement dates of August 2020. The future minimum lease payments aggregate \$0.9 million.

Through and including _____, 2020, (the 25th day after the date of this prospectus), all dealers effecting transactions in the Common Stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Shares



Tarsus Pharmaceuticals, Inc.

Common Stock

PROSPECTUS

BofA Securities

Jefferies

Raymond James

LifeSci Capital

Ladenburg Thalmann

, 2020

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

The following table presents the costs and expenses, other than underwriting discounts and commissions, payable in connection with this offering. All amounts are estimates except the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq Global Market listing fee. Except as otherwise noted, all the expenses below will be paid by us.

SEC registration fee	\$	*
FINRA filing fee		*
Nasdaq Global Market listing fee		*
Printing and engraving expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Transfer agent and registrar fees		*
Miscellaneous fees and expenses		*
Total	\$	*

* To be completed by amendment.

Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers under certain circumstances and subject to certain limitations. The terms of Section 145 of the Delaware General Corporation Law are sufficiently broad to permit indemnification under certain circumstances for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended (the "Securities Act").

As permitted by the Delaware General Corporation Law, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions relating to the limitation of liability and indemnification of directors and officers. The amended and restated certificate of incorporation provides that our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- in respect of unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- for any transaction from which the director derives any improper personal benefit.

Our amended and restated certificate of incorporation also provides that if Delaware law is amended after the approval by our stockholders of the certificate of incorporation to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law.

[Table of Contents](#)

Our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law, as it now exists or may in the future be amended, against all expenses and liabilities reasonably incurred in connection with their service for or on our behalf. Our amended and restated bylaws provide that we shall advance the expenses incurred by a director or officer in advance of the final disposition of an action or proceeding, and permit us to secure insurance on behalf of any director, officer, employee, or other enterprise agent for any liability arising out of his or her action in that capacity, whether or not Delaware law would otherwise permit indemnification.

We intend to enter into indemnification agreements with each of our directors and executive officers and certain other key employees, a form of which is attached as Exhibit 10.1. The form of agreement provides that we will indemnify each of our directors, executive officers and such other key employees against any and all expenses incurred by that director, executive officer, or other key employee because of his or her status as one of our directors, executive officers, or other key employees, to the fullest extent permitted by Delaware law, our restated certificate of incorporation and our amended and restated bylaws. In addition, the form agreement provides that, to the fullest extent permitted by Delaware law, we will advance all expenses incurred by our directors, executive officers and other key employees in connection with a legal proceeding.

Reference is made to the underwriting agreement contained in Exhibit 1.1 to this registration statement, indemnifying our directors and officers against limited liabilities. In addition, Section 2.8 of our amended and restated investors' rights agreement, or the IRA contained in Exhibit 4.2 to this registration statement provides for indemnification of certain of our stockholders against liabilities described in our IRA.

We currently carry and intend to continue to carry liability insurance for our directors and officers.

Item 15. Recent Sales of Unregistered Securities

The following list sets forth information regarding all unregistered securities sold by us since January 1, 2017. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

(a) From January 2017 through March 2018, we issued and sold to our directors, officers, employees, consultants and other service providers an aggregate of 19,890,000 shares of Common Stock at a price per share of \$0.0001 for an aggregate purchase price of \$1,989.

(b) From January 2017 through April 2020, we granted to our directors, officers, employees, consultants and other service providers stock options to purchase an aggregate of 8,727,355 shares of common stock upon the exercise of options under our 2016 Stock Plan at exercise prices per share ranging from \$0.0001 to \$0.27, for an aggregate exercise price of approximately \$1.4 million.

(c) In March 2018 and May 2018, we issued and sold an aggregate of 11,698,716 shares of our Series A Preferred Stock at a purchase price of \$0.312 per share for aggregate proceeds of approximately \$3.6 million.

(d) In May 2019, August 2019 and November 2019, we issued and sold convertible promissory notes in an aggregate principal amount of approximately \$2.0 million at face value (the "Notes").

(e) In December 2019, we issued and sold an aggregate of 49,578,623 shares of our Series B Preferred Stock at a purchase price of \$1.2104 per share for aggregate proceeds of approximately \$59.6 million (of which approximately \$57.6 million was cash and approximately \$2.0 million was cancellation of outstanding indebtedness in connection with the conversion of the Notes).

Table of Contents

The offers, sales and issuances of the securities described in Items (a) and (b) above were exempt from registration under the Securities Act under either (1) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (2) Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving any public offering. The recipients of such securities were the registrant's directors, officers, employees, consultants or other service providers and received the securities under our 2016 Stock Plan. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

The offers, sales and issuances of the securities described in Items (c), (d) and (e) above were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited person and had adequate access, through employment, business or other relationships, to information about the registrant.

Item 16. Exhibits and Financial Statement Schedules

(a) *Exhibits.* The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Description
1.1*	Form of Underwriting Agreement.
3.1*	Amended and Restated Certificate of Incorporation of Registrant, as currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation of Registrant, to be effective upon completion of this offering.
3.3*	Bylaws of Registrant, as currently in effect.
3.4*	Form of Amended and Restated Bylaws of Registrant, to be effective upon completion of this offering.
4.1*	Form of Registrant's common stock certificate.
4.2*	Amended and Restated Investors' Rights Agreement, dated December 13, 2019, by and among the Registrant and the other parties thereto.
5.1*	Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP.
10.1*	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.
10.2*	Tarsus Therapeutics, Inc. 2016 Stock Plan, as amended, and forms of agreements thereunder.
10.3*	Tarsus Therapeutics, Inc. 2020 Equity Incentive Plan and form of agreements thereunder.
10.4*	Tarsus Therapeutics, Inc. 2020 Employee Stock Purchase Plan.
10.5*	Office Lease, dated May 28, 2020, between the Registrant and Discovery Business Center LLC.
10.6*	Offer Letter, dated September 14, 2018, between the Registrant and Bobak Azamian, M.D., Ph.D.
10.7*	Offer Letter, dated March 15, 2020, between the Registrant and Leo M. Greenstein.
10.8*	Offer Letter, dated June 4, 2020, , between the Registrant and Seshadri Neervannan, Ph.D.
10.9*	Offer Letter, dated October 29, 2018, between the Registrant and Mark Holdbrook.
10.10*	License Agreement, dated January 31, 2019, between the Registrant and Elanco Tiergesundheits AG.

Table of Contents

<u>Exhibit Number</u>	<u>Description</u>
23.1*	Consent of Independent Registered Public Accounting Firm.
23.2*	Consent of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (contained in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).

* To be filed by amendment.

(b) *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 17. Undertakings

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

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Irvine, State of California, on this day of , 2020.

Tarsus Pharmaceuticals, Inc.

Bobak Azamian, M.D., Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Bobak Azamian and Leo M. Greenstein, and each of them, as his or her true and lawful attorney-in-fact and agent with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments) and any registration statement related thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent 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 for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute, may lawfully do or cause to be done by virtue hereof.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<hr/> Bobak Azamian, M.D., Ph.D.	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	
<hr/> Leo M. Greenstein	Chief Financial Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i>	
<hr/> Michael Ackermann, Ph.D.	Chairman	
<hr/> Bhaskar Chaudhuri, Ph.D.	Director	
<hr/> Andrew Goldberg, M.D.	Director	
<hr/> William J. Link, Ph.D.	Director	
<hr/> Jason Tester	Director	