UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39112

OYSTER POINT PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-1030955**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
202 Carnegie Center, Suite 109 Princeton, New Jersey	**08540**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (609) 382-9032

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.001	OYST	Nasdaq Global Select Market

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

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

The aggregate market value of the voting stock and non-voting common stock held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on December 31, 2019 as reported by the NASDAQ Global Select Market on such date, was approximately $168.0 million. The registrant has elected to use December 31, 2019, which was the last business day of the registrant's most recently completed fiscal

year, as the calculation date because on June 30, 2019 (the last business day of the registrant's most recently completed second fiscal quarter), the registrant was a privately-held company. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant, have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of February 21, 2020, the registrant had 21,366,950 shares of common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the 2020 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2019.

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OYSTER POINT PHARMA, INC.
Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2019

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report on Form 10-K 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 of initiation of our future clinical trials, and the reporting of data from our completed, current and future preclinical and clinical trials;
- our plans relating to the clinical development of our product candidates, including the size, number and disease areas to be evaluated;
- the size of the market opportunity and prevalence of dry eye disease (DED) for our product candidates;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- 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 DED and the number of patients that will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects 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;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications for which we may pursue;
- 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, 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 expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the proceeds from our initial public offering.

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

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases. Our lead product candidate OC-01 (varenicline), a highly selective nicotinic acetylcholine receptor (nAChR) agonist, is being developed as a nasal spray to treat the signs and symptoms of dry eye disease (DED). OC-01's novel mechanism of action is designed to re-establish tear film homeostasis by activating the trigeminal parasympathetic pathway and stimulating the glands and cells responsible for natural tear film production. In our Phase 2b clinical trial (ONSET-1) in 182 subjects, OC-01 demonstrated statistically significant improvements (as compared to placebo) in both signs and symptoms of DED in a single registrational clinical trial. Based on OC-01's clinical trial results and its rapid onset of action, we believe OC-01, if approved, has the potential to become the new standard of care and redefine how DED is treated for millions of patients. We initiated a Phase 3 clinical trial (ONSET-2) in July 2019 and expect to report top-line results by the end of the second quarter 2020. Based on the results from this second registrational trial, we plan to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2020. We believe that targeting the parasympathetic nervous system through the use of locally administered cholinergic agonists has the potential to treat a wide range of diseases and disorders. We have identified several indications, including several outside of ophthalmology, where we believe this approach could provide a meaningful benefit to patients.

DED is a multifactorial chronic disease of the ocular surface characterized by the loss of tear film homeostasis, resulting in pain, visual impairment, tear film hyperosmolarity and instability, inflammation, and corneal wounding. More than 340 million adults globally and approximately 34 million adults in the United States are estimated to suffer from DED. In the United States, DED is most commonly treated with a variety of over-the-counter eye drops, often referred to as "artificial tears," and three FDA-approved prescription eye drop therapies: Restasis, Xiidra and Cequa. Artificial tears are intended to supplement insufficient tear production or improve tear film instability, but are primarily saline-based and provide only temporary relief. Restasis and Cequa, both calcineurin inhibitor immunosuppressants, and Xiidra, a lymphocyte function-associated antigen-1 (LFA-1) antagonist, address chronic inflammation associated with DED. Despite the commercial uptake of these therapies—as examples, Restasis, marketed by Allergan, and Xiidra, recently acquired by Novartis, had U.S. sales in 2018 of $1.2 billion and $383 million, respectively—respondents in a survey we commissioned in June 2017 of 150 board-certified or board-eligible eye care practitioners (ECPs) were generally "neutral" or "completely disagreed" with the statement that they could, in their opinion, successfully treat all DED patients with the currently available treatment options whereas only 10% "completely agreed" with such statement. We estimate that of the approximately seven million patients who have started a prescription treatment to date, fewer than two million remain on prescription at any given time due to the significant limitations of these therapies, which include:

- *Mechanisms of action only address inflammation.* Currently approved therapies only target inflammation for moderate to severe DED; no approved pharmaceutical products replicate natural tear film, which is highly complex in composition. As these prescription therapies fail to address the fundamental characteristic of DED, the loss of tear film homeostasis, we estimate that 75% of patients still require over-the-counter therapies to supplement their treatment.

- *Slow onset of action*. Based on data reported from clinical trials, currently available treatments can take between three to six months to demonstrate a significant effect in clinical signs. We believe this delayed onset of action hinders compliance and in turn limits the benefit that patients derive from such treatments.

- *Tolerability and compliance issues.* Currently approved pharmaceutical therapies for DED are typically administered in an eye-drop formulation and are commonly associated with ocular burning, reduced visual acuity and bad taste after application. The effective use of eye drops can be challenging for some patients, and such challenges can result in reduced compliance.

To address these limitations and the high unmet need expressed by patients, ECPs and payors, we are developing a product candidate that we believe has the potential to become the new standard of care for DED. However, there is no guarantee that such product candidate will be approved by the FDA or, if approved, will provide revenues comparable to Restasis or Xiidra.

Our novel approach leverages the parasympathetic nervous system to promote natural tear film production and re-establish tear film homeostasis. Human tear film is a complex mixture of more than 1,500 different proteins, including antibodies, and numerous classes of lipids and mucins that are responsible for forming the primary refracting surface of the cornea, as well as protecting and moisturizing the cornea. The Lacrimal Functional Unit (LFU), which is controlled by the parasympathetic nervous

system, is comprised of glands and cells responsible for producing the three layers that comprise healthy tear film. To stimulate the LFU, we are targeting a class of receptors called nicotinic acetylcholine receptors (nAChR) that are located on the trigeminal nerve and readily accessible within the anterior nasal cavity. Administered as a preservative-free, aqueous nasal spray, OC-01's novel mechanism of action activates the trigeminal parasympathetic pathway to promote natural tear film production. We believe that increasing tear film volume and re-establishing tear film homeostasis will address the fundamental characteristic of DED, regardless of etiology, and has the potential to treat a broad population of patients throughout the dry eye continuum.

To date, we have treated over 500 subjects across five trials with OC-01 and OC-02 (simpinicline, which was formerly called simpanicline), our second nAChR agonist product candidate. We have consistently designed our clinical trials to be placebo (vehicle)-controlled, statistically rigorous and evaluated using pre-specified sign and symptom endpoints. In October 2018, we reported results from ONSET-1, a dose-ranging, randomized, double-masked, placebo-controlled, registrational Phase 2b clinical trial that evaluated the safety and efficacy of OC-01 in 182 subjects with DED in the United States. The study compared three different doses of OC-01 to placebo. The pre-specified primary (sign) endpoint was the assessment of tear production as measured by Schirmer's Score at Week 4 and the two pre-specified secondary (symptom) endpoints were patient-reported symptoms of DED as measured by Eye Dryness Score (EDS) at Weeks 3 and 4. These endpoints are consistent with those that have been previously utilized in clinical trials of FDA-approved products for DED. Results showed statistically significant improvements of the primary endpoint (Schirmer's Score) at all doses compared to placebo. In addition, results showed statistically significant improvements of the secondary endpoint (EDS) at Week 3 in the 0.6 mg/ml ($p=0.006$) and 1.2 mg/ml ($*p<0.001$) dose groups and at Week 4 in the 0.6 mg/ml ($p=0.021$) dose group. Moreover, OC-01 is designed to promote rapid production of tear film, and improvements in signs and symptoms were observed as quickly as five minutes after administration. OC-01 was well tolerated at all doses assessed in the study with no serious drug-related adverse events reported.

We met with the FDA in February 2019 for an end of Phase 2 meeting following the completion of ONSET-1, and the FDA indicated ONSET-1 could serve as one of the two pivotal safety and efficacy studies required to support an NDA filing for OC-01. Based on this feedback we initiated ONSET-2, a 750-subject, multicenter, randomized, double-masked, placebo-controlled Phase 3 trial, in July 2019. Assuming the effect size seen in ONSET-1, and based on this sample size, the power for each dose group for both sign and symptom endpoints would be 99% or greater. We expect to report top-line results from this second registrational trial by the end of the second quarter 2020 and, if successful, submit an NDA to the FDA in the second half of 2020.

We also completed a comparative pharmacokinetic "bridge" trial (ZEN) to evaluate the relative bioavailability of varenicline administered as a nasal spray (OC-01) compared to varenicline administered orally (Chantix). The FDA has indicated that reliance upon the varenicline tartrate data in our 505(b)(2) NDA submission would be considered scientifically justified if exposure levels following nasal spray administration of our final clinical formulation are less than or equal to that of Chantix at its approved dose and route of administration. We reported positive top-line results in November 2019 illustrating that the exposure levels following nasal spray administration are significantly lower than those seen with oral varenicline.

Leveraging our nAChR domain expertise, we continue to explore the development of OC-01 for a number of potential indications and uses associated with and beyond DED, including neurotrophic keratitis, dry eye associated with contact lens intolerance and ocular surface treatment for refractive surgeries. We have also studied OC-02 in two Phase 2b clinical trials in subjects with DED. However, we do not currently intend to pursue FDA approval for OC-02 in DED. We believe that targeting the parasympathetic nervous system through the use of locally administered cholinergic agonists has the potential to treat a wide range of diseases and disorders in the eye and systemically.

To execute on our vision to develop and commercialize a new standard of care for DED, we have assembled a team with extensive experience developing and commercializing leading ophthalmic products and therapies. Members of our management team have held senior positions at Allergan, Eyetech, Genentech, Johnson & Johnson, Novartis, Oculeve, Ophthotech, Pfizer, Pharmasset, and Shire. We intend to leverage this expertise and experience to rapidly pursue the development of OC-01, OC-02 and any other future product candidates that we may identify and develop. We also have leading financial investors which include New Enterprise Associates, Versant Ventures, Invus Opportunities, Flying L Ventures (investing through its Oyster Point Pharma I fund), KKR (investing through its Falcon Vision fund) and Vida Ventures.

Our Strategy

Our goal is to transform the treatment of DED and other ocular surface diseases by developing a broad portfolio of innovative therapies that target significant unmet medical needs. We intend to achieve this goal by pursuing the following key strategic objectives:

- **Completing development and obtaining approval of OC-01 for the treatment of DED.** OC-01 demonstrated statistically significant improvements (as compared to placebo) in both signs and symptoms of DED in a single registrational clinical trial. We are not aware of another therapy that has shown statistically significant improvements in both signs and symptoms of DED in a single registrational clinical trial. However, to date our trials have been designed as randomized, masked, placebo-controlled clinical trials and, as such, we have not tested OC-01 head-to-head with any other products or therapies, nor are we aware of any head-to-head results indicating that such other products or therapies could not have shown similar results. Based on the strength of the data observed in ONSET-1, our Phase 2b registrational clinical trial, we initiated a Phase 3 multicenter, randomized, double-masked, placebo-controlled clinical trial (ONSET-2). We expect to report top-line results from this second registrational trial by the end of the second quarter 2020 and, if successful, submit a 505(b)(2) NDA to the FDA in the second half of 2020.
- **Establishing our own specialty sales organization to commercialize OC-01 in the United States.** If OC-01 is approved for the treatment of the signs and symptoms of DED, we intend to commercialize our lead product candidate by deploying a specialty sales force at launch of approximately 150 to 200 field representatives targeting the top-prescribing ophthalmologists and optometrists. Given the importance of increasing awareness and educating patients with DED, we also anticipate deploying focused direct-to-consumer marketing campaigns for OC-01. We anticipate that this sales organization could also support the commercialization of additional product candidates treating ocular diseases.

- **Maximizing the value of OC-01 and our other product candidates outside the United States.** With more than 300 million additional DED patients outside of the United States, we believe there is a significant commercial opportunity for our product candidates internationally. To address these markets, we may seek one or more partners with regional capabilities and infrastructure to support and potentially accelerate the clinical development and commercialization of our product candidates, if approved, in such geographies.

- **Developing OC-01 for additional indications associated with and beyond DED.** Based on the fundamental role of natural tear film in ocular surface health, we plan to pursue development of OC-01 in other indications where this equilibrium is disturbed. First, we plan to pursue development for patients with neurotrophic keratitis, a degenerative disease resulting from a loss of corneal sensation, which causes progressive damage to the top layer of the cornea. As natural tear film contains a myriad of beneficial components, including endogenous growth factors, proteins and antibodies, we believe that our product candidate could be beneficial in improving the health of the cornea in these patients. A second population of potential clinical benefit is in subjects with DED associated with contact lens intolerance. In addition, based on the unique characteristics of this product candidate, we see the potential for use in patients that are preparing for refractive surgery where there is often an underlying dry eye condition that could impact refraction and ultimately patient satisfaction and quality of life post-surgery.

- **Leveraging the capabilities of our experienced discovery and development team and our nAChR domain expertise to continue expanding our pipeline of product candidates.** We have studied a second nAChR agonist product candidate OC-02 (simpinicline) in two Phase 2b clinical trials for DED. We have identified several indications, other than DED, where we believe this product candidate has the potential to provide a meaningful benefit to patients. In certain indications, we believe OC-02 could advance directly into a Phase 2 proof of concept study, supported by preclinical and clinical data that we and others have generated. However, we cannot guarantee that the FDA will permit us to advance OC-02 into a Phase 2 proof of concept study nor can we guarantee that the FDA will grant marketing approval to OC-02 for the treatment of any indication. Beyond OC-02, we plan to continue our efforts to identify and develop additional product candidates.

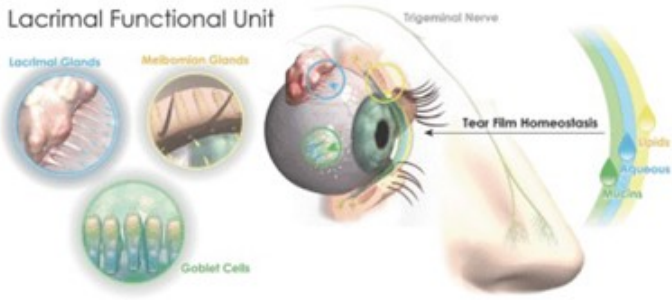
- **Selectively evaluating external opportunities to expand the scope of our pipeline or product offerings.** We may pursue acquisition or in-licensing of product candidates, particularly in our core disease area of ocular surface diseases.

Dry Eye Disease Overview

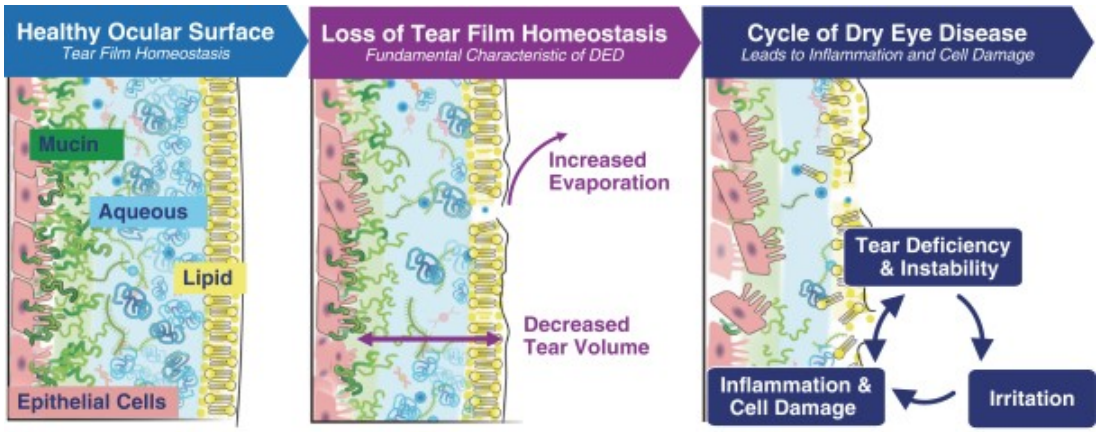
Dry eye disease (DED) is a multifactorial, age-related chronic progressive disease of the ocular surface resulting in pain, visual impairment, tear film hyperosmolarity and instability, and inflammation. Patients with DED are also more susceptible to eye infections and damage to the surface of the eye (cornea). DED is characterized by a reduction in tear volume, rapid breakup of the tear film, or an increase in the evaporative properties of the tear film layer. DED affects daily life, including reading and

driving at night and has been associated with depression and migraines. DED can also limit patients' ability to tolerate contact lenses and impacts patient satisfaction with post-op cataract and refractive patients.

As illustrated below, the Lacrimal Functional Unit (LFU), which is controlled by the parasympathetic nervous system, is comprised of Meibomian glands, lacrimal glands, and goblet cells that are responsible for producing the three layers that comprise healthy tear film. The National Eye Institute defines healthy tear film as "a complex mixture of fatty oils, water, mucus, and more than 1,500 different proteins that keep the surface of the eye smooth and protected from the environment, irritants, and infectious pathogens." The outermost layer of tear film is a lipid layer produced by the Meibomian glands that keeps tear film from evaporating too quickly. The lacrimal glands produce the aqueous layer, which comprises the bulk of tear volume and flow. This middle layer is not just water – it contains thousands of proteins, enzymes, antibodies and growth factors that are cytoprotective, anti-inflammatory, and anti-microbial. The aqueous layer nourishes the cornea and the conjunctiva, the mucous membrane that covers the entire front of the eye and the inside of the eyelids. Finally, the innermost mucin layer is produced by goblet cells and binds water from the aqueous layer to ensure that the eye remains wet. The LFU receives stimulus from the trigeminal nerve, which has sensory nerve endings in the nasal cavity.



LFU dysfunction leads to the loss of tear film homeostasis and can ultimately lead to the cycle of chronic DED. Disruption and instability of the tear film results in irritation, inflammation, and ultimately cellular damage. Chronic symptoms of DED include a scratchy sensation (foreign body sensation), stinging or burning, episodes of excess tearing that follow periods of dryness, discharge, pain, and redness in the eye. In addition, patients with dry eye often experience blurred vision as the cornea and the tear film are responsible for 65%-75% of the eye's focusing power. Approved prescription treatments for DED, as well as therapies in clinical development, target inflammation further down the DED continuum. We believe these therapies only treat patients with moderate to severe DED and do not address the loss of tear film homeostasis, the fundamental characteristic of DED. Our lead product candidate OC-01 is designed to stimulate the LFU to produce natural tear film, re-establish tear film homeostasis and improve the signs and symptoms of patients with DED.



Market opportunity in DED

DED is highly prevalent and growing, currently affecting more than 340 million people globally. In the United States, DED affects an estimated 14.5% of the adult population, or 34 million adults, resulting in greater than $55 billion in annual indirect costs, such as reductions in productivity. Prevalence of DED continues to grow due to an aging population, increase in autoimmune diseases, contact lens wear and digital screen time. Although DED is one of the most common reasons people visit an ECP in the United States, it is estimated that only 16 million adults have been diagnosed with DED by an ECP, which we believe is due in part to lack of education and insufficient awareness on the part of the patient.

Despite the number of patients diagnosed with DED, we estimate that only seven million patients to date have started a prescription treatment regimen which we believe is based at least in part on a lack of treatment options that are suitable for chronic use. In a survey we commissioned in June 2017 (the ECP Survey) of eye care practitioners (ECPs), respondents were generally neutral or dissatisfied with their treatment options for patients with DED. The ECP Survey was conducted by means of a distributed questionnaire to 150 respondent ECPs who specialize primarily in ophthalmology or optometry, are board-certified or board-eligible, manage at least 40 unique patients per month with DED and are familiar with, or prescribe, currently available prescription therapies. In the ECP Survey, we asked ECPs to select whether they completely disagreed, were neutral or completely agreed with the statement that they "can successfully treat all Dry Eye patients with currently available options." Approximately 40% of ECPs responded that they completely disagreed with the statement, approximately 50% responded that they were neutral and only 10% responded that they completely agreed. Similarly, the top clinical reasons patients discontinued therapy were insufficient symptom improvement, side effects, and delayed onset of action. Medication cost was also a factor in discontinuing therapy. However, in our survey of patients who had discontinued Restasis due to costs, 72% stated they would have been willing to pay the same price if the medication had worked better. As a result of these factors, we believe that only two million patients are on a prescription therapy at any given time. Despite the small percentage of DED patients on prescription therapy, Restasis (marketed by Allergan) and Xiidra (recently acquired by Novartis for a total consideration of up to $5.3 billion) had U.S. sales in 2018 of $1.2 billion and $383 million, respectively. However, we cannot guarantee that OC-01 or any of our other future product candidates will be approved by the FDA and, even if one of our product candidates is approved, there is no guarantee that our revenues will be comparable to those of Restasis or Xiidra.

Current treatment options and their limitations

DED is primarily treated with a variety of over-the-counter eye drops, often referred to as "artificial tears," and three FDA-approved prescription eye drop therapies: Restasis, Xiidra and Cequa. Artificial tears are intended to supplement insufficient tear production or improve tear film instability, but are primarily saline-based and provide only temporary relief. Restasis and Cequa, both calcineurin inhibitor immunosuppressants, and Xiidra, a lymphocyte function-associated antigen-1 (LFA-1) antagonist, which has been approved for the treatment of the signs and symptoms of DED, address chronic inflammation associated with DED. Other treatment options include ointments, gels, warm compresses, omega-3 fatty acid supplements and a number of medical devices. Unfortunately, all currently approved treatment options for DED have significant limitations, which include:

- *Mechanisms of action only address inflammation.* Currently approved therapies only target inflammation for moderate to severe DED; no approved pharmaceutical products replicate natural tear film, which is highly complex in composition. As these prescription therapies fail to address the fundamental characteristic of DED, the loss of tear film homeostasis, we estimate that 75% of patients still require over-the-counter therapies to supplement their treatment.

- *Slow onset of action*. Based on data reported from clinical trials, currently available treatments can take between three to six months to demonstrate a significant effect in clinical signs. We believe this delayed onset of action hinders compliance and in turn limits the benefit that patients derive from such treatments.

- *Tolerability and compliance issues.* Currently approved pharmaceutical therapies for DED are typically administered in an eye-drop formulation and are commonly associated with ocular burning, reduced visual acuity and bad taste after application. The effective use of eye drops can be challenging for some patients and result in reduced compliance.

To address these limitations and the high unmet need expressed by patients, ECPs and payors, we have been developing OC-01, which we believe, if approved, has the potential to become the new standard of care for DED. However, there is no guarantee that it will provide revenues comparable to existing treatments. OC-01's highly differentiated mechanism of action is designed to re-establish tear film homeostasis, addressing the fundamental disease process, regardless of stage of disease or underlying cause. We are not aware of any other drug companies focused on activating the trigeminal parasympathetic pathway (TPP) and stimulating the LFU to increase tear production. OC-01 has demonstrated rapid onset of action to significantly improve signs and symptoms in the same patient population within a single registrational clinical trial. Furthermore, the novel delivery of

OC-01 in a nasal spray spares the ocular surface and contributes to a favorable tolerability profile. To date, there have been no reports of burning or stinging to the ocular surface or negative effects on taste or smell in clinical trials of OC-01. We believe OC-01, if approved, has the potential to offer improved clinical outcomes and patient compliance based on its registrational trial results, favorable tolerability profile and rapid onset of action, therefore making it particularly suitable for use broadly across mild, moderate and severe patient populations.

Our approach: activating the trigeminal parasympathetic pathway to promote natural tear film production

To address these limitations and the high unmet need expressed by patients, ECPs and payors, we are developing a product candidate that we believe has the potential to serve as the new standard of care for DED. Our novel approach is designed to leverage the parasympathetic nervous system to stimulate natural tear film production and re-establish tear film homeostasis. A healthy tear film protects and lubricates the eyes, washes away foreign particles, contains antimicrobials to reduce the risk of infection, and creates a smooth surface that contributes refractive power for clear vision.

The Trigeminal Parasympathetic Pathway

The parasympathetic nervous system (PNS) is a division of the autonomic nervous system and is responsible for actions such as stimulating gland function, constriction of the pupil, slowing down heart rate and contractility, contracting bronchial musculature and stimulating bronchial secretions, and increasing gut motility for digestion. The parasympathetic nervous system controls tear film homeostasis and the activity of the LFU partially via the trigeminal nerve. The PNS uses acetylcholine (ACh) as its neurotransmitter.

Anesthetizing the nasal mucosa has been shown to result in a 34% reduction in tear film production. This has also been observed in patients with reduced nasal air flow resulting from severe nasal allergy and patients with tracheostomy, suggesting that stimulation of the trigeminal nerve is important for tear production. Since then, additional studies have demonstrated a persistent decrease in aqueous tear production in patients with trigeminal nerve damage (such as trauma, trigeminal nerve ablation and herpetic infection) or pathology.

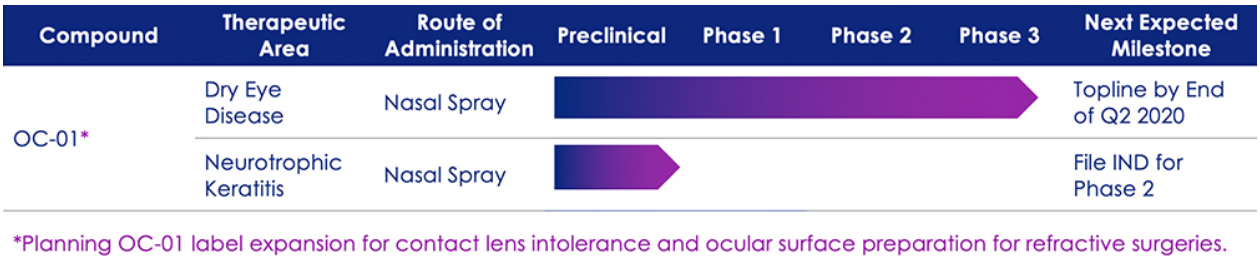
We refer to the communication between the trigeminal nerve and the LFU as the TPP. The efferent paths (away from the nose) of the TPP proceed from the superior salivary nucleus along the facial nerve to the geniculate ganglion and from there through the greater superficial petrosal nerve via the sphenopalatine ganglion to the LFU. Activating the TPP results in the stimulation of the Meibomian glands, lacrimal glands (main and accessory), and goblet cells comprising the LFU and promotes natural tear film production.

Targeting nicotinic acetylcholine receptors (nAChR) on the trigeminal nerve

Our approach to DED relies on a pharmaceutical stimulation of a class of receptors called nicotinic acetylcholine receptors (nAChR) that are located on the trigeminal nerve and readily accessible within the anterior nasal cavity. nAChRs are ligand-gated ion channels that when bound by an agonist have the potential for ganglionic neurotransmission. The nAChRs subtypes found on human neurons are comprised of various homomeric (all one subunit) or heteromeric (at least one α and one ß subunit) combinations of 12 different nicotinic receptor subunits: α2-α10 and ß2-ß4. Stimulation of these receptors results in a rapid increase in cellular permeability to Na^{+} and Ca^{2+} resulting in depolarization of the cell membrane and initiation of an action potential. However, not all subtypes of nAChRs have the ability to activate the TPP (for example, treatment with a homomeric α7 agonist has no effect on this pathway). Additionally, the functional response of an nAChR to agonists is comprised of two dose-dependent, opposing effects: receptor activation after short exposure to high agonist concentrations (µM range), and desensitization upon prolonged exposure to low agonist concentrations (nM range).

Our product candidates OC-01 and OC-02 contain APIs that are highly selective to the nAChRs that activate the TPP. We believe this is the first application of nAChR agonists to be delivered nasally to stimulate the nerves of the PNS. Additionally, we have found that OC-01 and OC-02's unique receptor binding characteristics and the localized nasal delivery allows for short-term agonist exposure with a high local concentration, and, once absorbed across the nasal mucosa, results in low systemic exposure and therefore avoids desensitization.

Our Product Candidates



OC-01 (varenicline) nasal spray for Dry Eye Disease

Our lead product candidate OC-01 is being developed as a nasal spray to treat the signs and symptoms of DED. The API of OC-01, varenicline, is a highly selective nicotinic acetylcholine receptor (nAChR) agonist with full agonist activity at the α7 receptor and partial agonist activity at the α3ß4, α3α5ß4, α4ß2, and α4α6ß2 receptors. Varenicline tartrate, marketed as Chantix, was developed and commercialized by Pfizer as an aid to smoking cessation treatment. The compound was studied in multiple dose-ranging, placebo-controlled Phase 2 studies as well as two confirmatory Phase 3 studies to study the safety and efficacy in otherwise healthy smokers in the United States. In 2006, varenicline was approved by both the FDA and the European Medicines Agency and subsequently has been approved in more than 80 other countries throughout the world. To date, varenicline oral tablets have been prescribed to more than 20 million patients worldwide, including more than 11 million adults in the United States.

OC-01 is a preservative-free, aqueous nasal spray designed to be delivered twice daily to each nostril in a 50 µl spray for the treatment of dry eye disease. The highest intranasal concentration of varenicline being studied in ONSET-1 and ONSET-2 is 1.2 mg/ml, approximately ten-fold lower than the maintenance dose of Chantix (2 mg/day) on a nominal daily dosing basis. The lower dose of 0.6 mg/ml varenicline being studied in these two registrational trials is approximately 20-fold lower than the maintenance dose of oral Chantix on a nominal daily dosing basis.

OC-01's novel mechanism of action

OC-01's novel mechanism of action is designed to re-establish tear film homeostasis by stimulating the trigeminal nerve, activating the TPP and stimulating the glands and cells responsible for natural tear film production. We believe that the development of OC-01 as a nasal spray represents the first pharmacological treatment approach for DED targeting the nerves that control the LFU. OC-01, when sprayed into the anterior portion of the nasal cavity, stimulates nAChRs located on the chemosensory endings of the trigeminal nerve resulting in cholinergic neurotransmission.

Once OC-01 is bound to an nAChR, it stabilizes the open state of the ion channel allowing influx of cations such as Ca^{2+} and Na^{+} ions, thus creating an action potential. This action potential ultimately activates the glands and cells of the LFU to produce natural tear film. Once the nasal spray is delivered, it takes approximately 10-15 seconds before tear film is produced. The receptors can be in the activated state for many minutes to hours after stimulation (a process termed smoldering activation).

We believe that increasing tear film volume and re-establishing tear film homeostasis will address the fundamental characteristic in the development and treatment of DED, regardless of etiology, and has the potential to treat a broad population of patients throughout the dry eye continuum.

Our development program for OC-01

In October 2018, we reported results from ONSET-1, a multicenter, dose-ranging, randomized, double-masked, placebo (vehicle)-controlled, registrational Phase 2b clinical trial that evaluated the safety and efficacy of OC-01 in 182 subjects with DED in the United States. Following ONSET-1, we initiated a Phase 3 registrational clinical trial (ONSET-2) in July 2019 and expect to report top-line results by the end of the second quarter 2020.

We also completed a comparative pharmacokinetic "bridge" trial (ZEN) to evaluate the relative bioavailability of varenicline administered as a nasal spray (OC-01) compared to varenicline administered orally (Chantix) and reported top line results in November 2019. The exposure levels following nasal spray administration of varenicline are significantly lower than those seen with oral varenicline. If the FDA determines that the results of this trial establish an adequate bridge between OC-01 and Chantix, it will allow us to reference certain FDA conclusions regarding the safety of varenicline from the Agency's review of the Chantix

NDA. If both ONSET-2 and ZEN are successful, we intend to submit the results of ONSET-2 and ZEN together with the results from ONSET-1 as part of a 505(b)(2) NDA to the FDA in the second half of 2020.

In January 2020, we reported results from MYSTIC, a randomized, single-masked, vehicle-controlled Phase 2 clinical trial that evaluated the safety and efficacy of OC-01 in 123 subjects with DED. The goal of this study was to assess the safety and efficacy of twice daily dosing of OC-01 nasal spray administered for 84 days. Although the study will add to the totality of the data in support of the efficacy of OC-01 nasal spray in subjects with DED, the MYSTIC data will only be used to support the safety of OC-01 in terms of NDA submission.

Statistical Significance

In the description of our clinical trials below, n represents the number of patients in a particular group and p or p-values represent the probability that random chance caused the result (e.g., a p-value=0.001 means that there is a 0.1% probability that the difference between the placebo group and the treatment group is purely due to random chance). A p-value ≤ 0.05 is a commonly used criterion for statistical significance, and may be supportive of a finding of efficacy by regulatory authorities. The confidence interval (CI) means a range of values for a variable of the measure of treatment effect, constructed so that this range has a specified probability of including the true value of the variable.

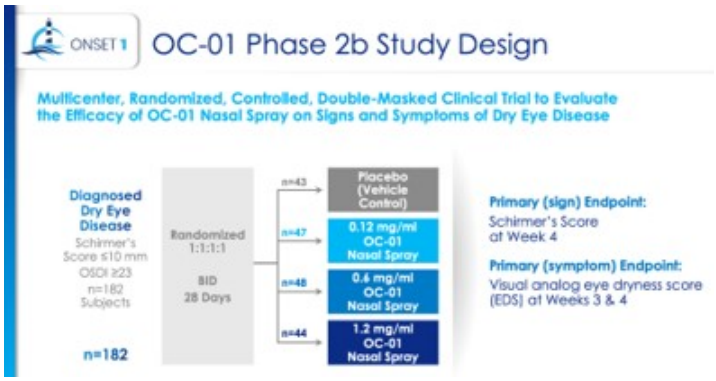
ONSET-1: Phase 2b clinical trial results

In ONSET-1, OC-01 demonstrated statistically significant improvements in both signs and symptoms of DED. The study compared three different doses of OC-01 to placebo. The pre-specified primary (sign) endpoint was the assessment of tear production as measured by Schirmer's Score (compared to the baseline Schirmer's Score) at Week 4 and the two pre-specified secondary (symptom) endpoints were patient-reported symptoms of DED as measured by EDS at Weeks 3 and 4. We also evaluated corneal fluorescein staining, a marker of corneal epithelial cell health, at Week 4, as an exploratory endpoint in ONSET-1. Due to the relatively small sample size of the study and the use of the controlled adverse environment chamber (CAE) that can exacerbate staining, ONSET-1 was not designed or powered to assess statistical significance for this endpoint. Baseline disease characteristics were generally similar across all treatment groups, with the exception of the 1.2 mg/ml OC-01 dose group where lower average disease severity was observed as indicated by a higher mean Schirmer's test (5.5 mm) relative to the other dose groups (range: 4.5 to 5.2 mm) and a lower mean EDS (53.5 mm) relative to the other dose groups (range: 63.7 to 65.6 mm).

Although we cannot guarantee that the FDA will grant marketing approval for OC-01 based on the use of these endpoints, ONSET-1's pre-specified endpoints are consistent with those that have been previously utilized in clinical trials of FDA-approved products for DED. The Schirmer's Score, which was the same primary sign endpoint used in the FDA's approval of Restasis, is determined by placing a test strip in the lower eyelid pouch and measuring the length of the test paper strip that is moistened after five minutes. Sometimes a topical anesthetic is placed into the eye before the filter paper to prevent tearing due to the irritation from the paper. The study eye was pre-defined as the eye that met eligibility criteria in the study and in the event that both eyes met criteria, was the eye with more tearing at baseline upon stimulation or in the event that both eyes were again equal, the eye with the worse baseline Schirmer's Score. The fellow eye is the eye that was not defined as the study eye and may or may not have met all study eligibility criteria. The EDS, which was the primary symptom endpoint used in the FDA's approval of Xiidra, is based on the patient's rating of eye dryness on a visual analog scale (where 0=no discomfort and 100=maximal discomfort) with respect to both eyes. The study was designed and pre-specified to statistically analyze the 0.6 mg/ml and 1.2 mg/ml OC-01 dose groups. The study was not designed to formally analyze the 0.12 mg/ml dose group to avoid spending statistical power on a dose that was not hypothesized to provide clinically meaningful results. Therefore, no p-value is formally reported for the 0.12 mg/ml dose group.

The study design is included below:

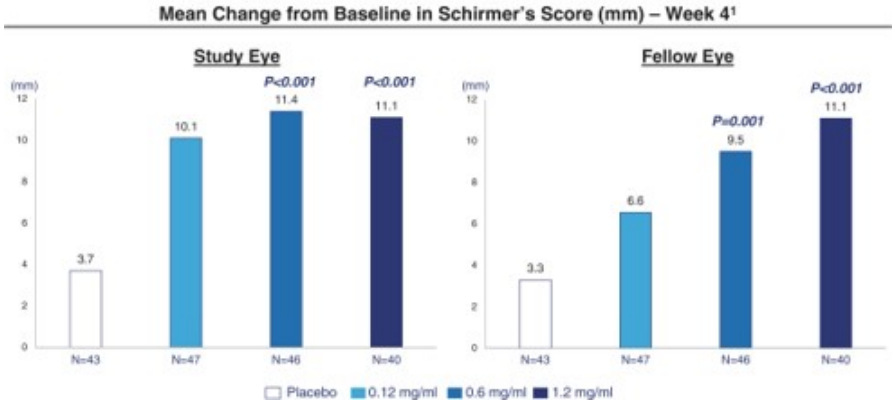
Figure 1. ONSET-1 Study Design



In ONSET-1, the 182 subjects were randomly sorted into the four treatment groups following assessment of each subject's baseline Schirmer's Score and EDS. The mean baseline disease characteristics across all treatment groups were generally similar with the exception of the 1.2 mg/ml OC-01 dose group. In this group, subjects showed lower baseline disease severity, with a higher mean Schirmer's Score (5.5 mm) relative to the other dose groups (range: 4.5 to 5.2 mm) and a lower mean EDS (53.5 mm) relative to the other dose groups (range: 63.7 to 65.6 mm).

As shown in Figure 2, a statistically significant improvement in Schirmer's Score at Week 4 was observed in all three doses compared to placebo. The 0.6 mg/ml was associated with a least squares (LS) mean change from baseline Schirmer's Score of 11.4 mm (95% CI 8.9-13.9; p<0.001). The 1.2 mg/ml dose group was associated with a LS mean change from baseline Schirmer's Score of 11.1 mm (95% CI 8.5-13.7; p<0.001). The 0.12 mg/ml dose group was not formally tested, although it was associated with a LS mean change from baseline Schirmer's Score of 10.1 mm. Anesthetized Schirmer's Score results were similar in the fellow eyes of subjects (p<0.01).

Figure 2. ONSET-1: Primary (Sign) Endpoint



[1]ANCOVA, Least Squares mean. ITT-observed population. Analysis of Covariance (ANCOVA) is a general linear statistical model which blends analysis of variance and regression. Intent to Treat (ITT) population analysis is an analysis of all randomized subjects, regardless of whether they received study treatment.

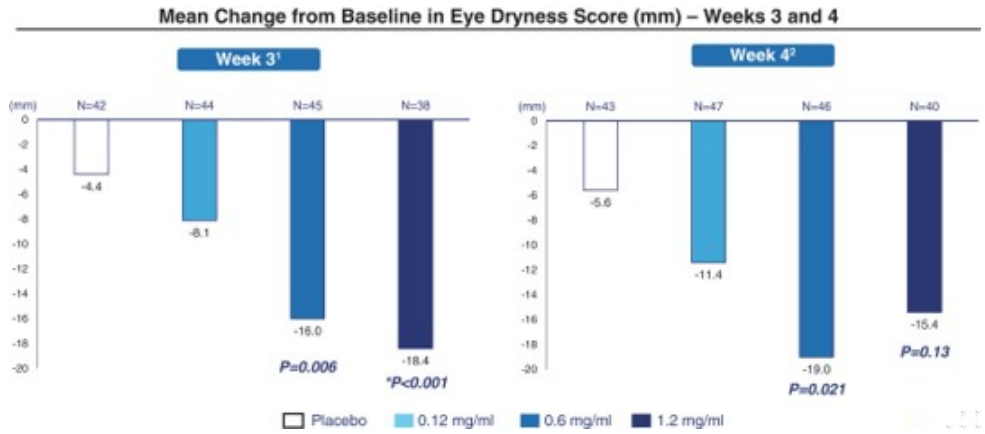
The proportion of subjects who had a change of greater than or equal to (or ≥) 10 mm in Schirmer's Score from baseline at Week 4 was statistically significantly higher compared to subjects treated with placebo (vehicle nasal spray; 6 of 43 subjects, 14%) in the 0.6 mg/ml (25 of 46 subjects, 54%; 95% CI 40-69; P<0.001) and 1.2 mg/ml (19 of 40 subjects, 48%; 95% CI 32-63; P=0.001) dose groups. Similar changes from baseline were observed for the OC-01 0.12 mg/ml group (21 of 47 subjects, 45%; 95% CI 30-59; P=0.001).

ONSET-1 had two pre-specified secondary endpoints. The first secondary endpoint was the mean change from baseline to Week 4 in EDS (both eyes). As shown in Figure 3, a statistically significant reduction in mean EDS from baseline to Week 4 was

observed in the 0.6 mg/ml dose group, with a LS mean change from baseline EDS of -19.0 mm (95% CI -26.2 to -11.7; p=0.021). The LS mean change from baseline EDS to Week 4 for the 1.2 mg/ml dose group was -15.4 mm (95% CI -23.3 to -7.5; p=0.13).

The other secondary endpoint was the change from baseline to Week 3 in mean EDS at five minutes post treatment in the CAE. As shown in Figure 3, a statistically significant reduction in mean EDS from baseline to Week 3 at five minutes post treatment in CAE was observed in the 0.6 mg/ml dose group, with a LS mean change from baseline EDS of -16.0 mm (95% CI -21.3 to -10.6; p=0.006). The LS mean change from baseline EDS to Week 3 at five minutes post treatment in CAE for the 1.2 mg/ml dose group was -18.4 mm (95% CI -24.3 to -12.5, *p<0.001). As the first secondary outcome was statistically different from placebo only in the 0.6 mg/ml dose group, change in EDS was formally tested in that dose group alone. At Week 3, in the CAE, the LS mean difference in change from baseline of the EDS between the 0.6 mg/ml dose and placebo groups at five minutes post treatment in CAE was -11.6 mm (95% CI -20.1 to -3.0; p=0.006). The LS mean difference between the 1.2 mg/ml dose and placebo groups in the change from baseline EDS was -14.0 mm (95% CI -22.9 to -5.1). While no formal analysis was performed on the 1.2 mg/ml dose group, as this dose group was not statistically significant in the first secondary endpoint, the nominal p-value was p<0.001.

Figure 3. ONSET-1: Secondary (Symptom) Endpoints



[1] ANCOVA, Least Squares mean. ITT-observed population. Controlled Adverse Environment (CAE).

[2] ANCOVA, Least Squares mean. ITT-observed population.

[*] Nominal p-value

Sensitivity analyses at ten and fifteen minutes post treatment in the CAE showed similar reductions in EDS as those seen at five minutes post treatment in subjects treated with OC-01 compared to subjects treated with placebo.

ONSET-1 was not designed or powered to assess corneal fluorescein staining, although we did ultimately measure this as an exploratory analysis using the National Eye Institute Corneal Fluorescein grading scale. This scale measures corneal staining in five distinct regions on the cornea: central, superior, inferior, nasal, and temporal, as well as a total score that includes all regions. At Week 4, in the 0.6 mg/ml dose group, total corneal staining (95% CI -2.9 to -0.2; p=0.020), nasal corneal staining (95% CI -0.8 to -0.0; p=0.026), and inferior corneal staining (95% CI -0.8 to -0.1; p=0.006) showed a statistically significant benefit as compared to placebo. There was a directional benefit in the 0.6 mg/ml dose group favoring OC-01 in central, superior, and temporal staining as compared to placebo. We believe that this is the only registrational study to show a statistically significant benefit in corneal fluorescein staining as soon as Week 4. There was no statistically significant benefit in corneal fluorescein staining in 1.2 mg/ml dose group, although there was a directional benefit favoring OC-01 in total, central, temporal, inferior, and nasal staining as compared to placebo.

OC-01 was well tolerated at all doses assessed in the study with only one serious adverse event reported (in the 0.6 mg/ml dose), which was not suspected to be related to the study drug. The most commonly reported drug-related adverse events in ONSET-1 were non-ocular, whereas reports of ocular adverse events were few and transient. Only one subject each in the 0.12 mg/ml and 1.2 mg/ml dose groups and two subjects in the 0.6 mg/ml dose group reported ocular adverse events compared to seven subjects in the placebo group. Of these reported events, reduced visual acuity was reported by one subject each in the 0.12 mg/ml and 0.6 mg/ml dose groups compared to three subjects in the placebo group, and each instance of reduced visual acuity reported was resolved by the next visit. No other ocular adverse event was reported by more than one subject.

Four subjects discontinued the study due to adverse events. One subject in the 0.6 mg/ml dose group withdrew from the study after one day of treatment due to dizziness. Three subjects in the 1.2 mg/ml dose group withdrew from the study. The first subject withdrew from the 1.2 mg/ml dose group after one day of treatment due to sneezing and throat irritation. The other two subjects withdrew from the 1.2 mg/ml dose group after two days of treatment due to (i) nasopharyngitis and (ii) tinnitus, headache and eyelid edema, respectively. No subjects withdrew from the study after the second day of treatment. The most commonly reported non-adverse events in ONSET-1 were sneezing and coughing, as shown in Figure 4 below. No subjects in the placebo group reported either sneezing or cough.

Figure 4. Non-Ocular Adverse Events Occurring in More than One Subject in any Treatment Group

System Organ Class (1) High level Term Preferred Term	OC-01 0.12 mg/ml (n=47) n (%)	OC-01 0.6 mg/ml (n=48) n (%)	OC-01 1.2 mg/ml (n=44) n (%)	Placebo n=43 n (%)
Subjects with Non-Ocular Adverse Events	33 (70)	44 (92)	41 (93)	5 (12)
Nervous System Disorders				
Headache	0	0	2 (5)	1 (2)
Respiratory				
Upper Respiratory tract and symptoms	29 (62)	39 (81)	38 (86)	2 (5)
Sneezing	29 (62)	38 (79)	37 (84)	0
Throat irritation	0	7 (15)	9 (20)	0
Cough	4 (9)	6 (13)	11 (25)	0
Dysaesthesia pharynx	5 (11)	4 (8)	3 (7)	0
Nasal Dryness	1 (2)	0	0	2 (5)
General				
Applications and Instillation Site Reactions	3 (6)	9 (19)	9 (20)	0
Instillation Site Irritation	3 (6)	8 (17)	8 (18)	0

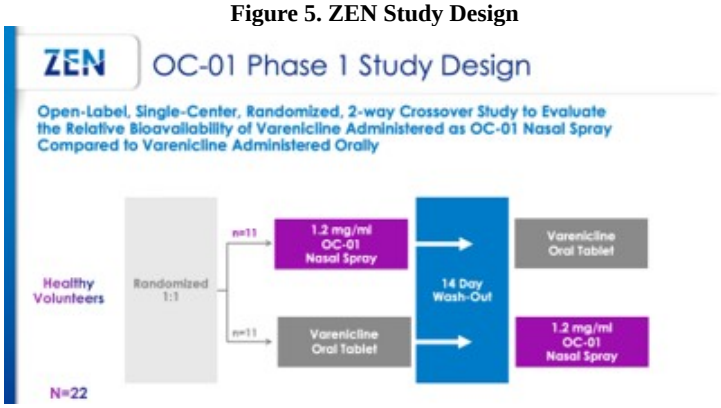
(1)Column header counts and denominators are the number of treated subjects. Subjects are counted at most once within each Medical Dictionary for Regulatory Activities system organ class and preferred term row.

Based on OC-01's clinical trial results in ONSET-1 and its rapid onset of action, we believe that OC-01, if approved, has the potential to become the standard of care and redefine how DED is treated for millions of patients.

ZEN: Phase 1 comparative pharmacokinetic clinical trial results

We completed a comparative pharmacokinetic "bridge" trial (ZEN) where we evaluated the relative bioavailability of varenicline administered as a nasal spray (OC-01) compared to varenicline administered orally (Figure 5). We reported positive top-line results in November 2019. ZEN is a Phase 1, open-label, randomized, two-way crossover study to evaluate the relative bioavailability of OC-01 compared to varenicline administered orally. The study design is included below:

Figure 5. ZEN Study Design



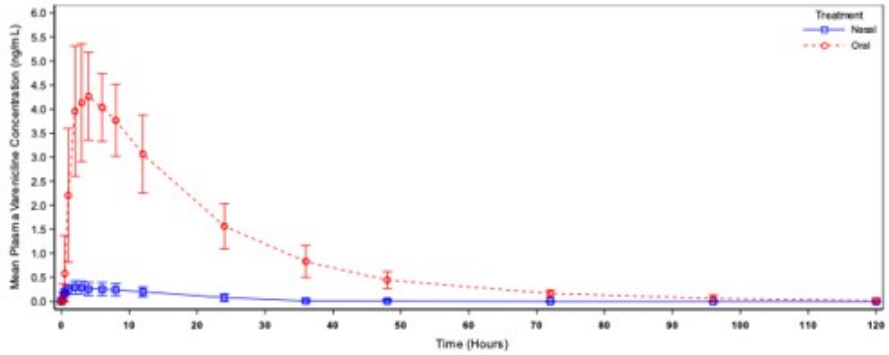
The ZEN study was designed to assess the relative bioavailability of varenicline administered intranasally at its highest intended clinical strength (1.2 mg/ml in a 50 microliter nasal spray) compared to varenicline administered as a single oral dose at

its commercially available maintenance oral tablet strength (1 mg). The treatment cohort consisted of 22 healthy volunteers between 18-65 years of age meeting all other study eligibility criteria who were randomized (Treatment Period 1) to receive an intranasal dose of 0.12 mg OC-01 (50 µL spray of 0.06 mg into each nostril) or a single 1 mg oral dose of varenicline. Both administrations were delivered while the subject was in an overnight fasted state. Subjects then returned at least 14 days later (Treatment Period 2) to receive the alternate dose of varenicline that was delivered at Treatment Period 1.

Top-line results (Figure 6) indicate that the relative bioavailability (systemic exposure as defined by adjusted geometric mean AUC0-inf) was 13 times lower for a single dose of the highest strength of OC-01 nasal spray as compared to a single dose of the highest strength varenicline tablet (7.46 vs. 99.67 h*ng/ml). Maximal concentration (as defined by adjusted geometric mean Cmax) was 14 times lower for a single dose of the highest strength of OC-01 nasal spray as compared to a single dose of the highest strength varenicline tablet (0.32 vs. 4.55 ng/ml).

The study demonstrated that OC-01 nasal spray was safe and well-tolerated at the doses tested. The number of subjects reporting any treatment-emergent adverse event (TEAE) was 13 out of 21 (61.9%) after nasal spray administration and 9 out of 22 (40.9%) after oral tablet administration but there were no reports of serious TEAE noted with either oral or nasal administration. The most common adverse events in the nasal spray group were sneeze in 7 volunteers (33.3%) and cough in 6 volunteers (28.6%). All events were mild. There were no events of sneeze or cough in the oral tablet administration group. The most common adverse events in the oral tablet administration group were nausea in 5 volunteers (22.7%) and vomiting in 4 volunteers (18.2%). All events were mild or moderate in severity. There were no events of nausea or vomiting in the nasal spray administration group.

Figure 6. ZEN Study Results: Mean (+/-SD) Systemic Exposure for Nasal Varenicline and Oral Varenicline



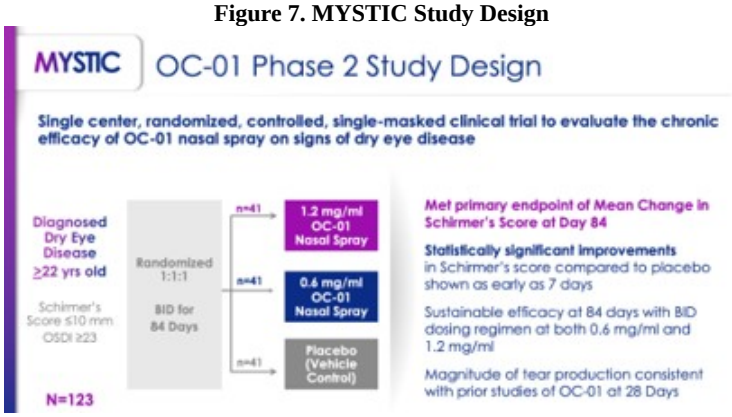
Plasma concentration values below the LLOQ (0.1) are presented as '0' (zero) in the arithmetic mean calculations.
Treatment A: Single oral dose of 1 mg varenicline (Chantix®) administered orally;
Treatment B: Intranasal dose of 0.12 mg OC-01 (varenicline)- delivered as a 50 µL (0.06 mg) spray into each nostril.

This trial could allow us to reference certain FDA conclusions regarding the safety of varenicline tartrate from the Agency's review of the Chantix NDA. The FDA has indicated that reliance upon the varenicline tartrate data in our 505(b)(2) NDA submission would be considered scientifically justified if exposure levels following nasal spray administration of our final clinical formulation are less than or equal to that of Chantix at its approved dose and route of administration.

MYSTIC: Phase 2 clinical trial results

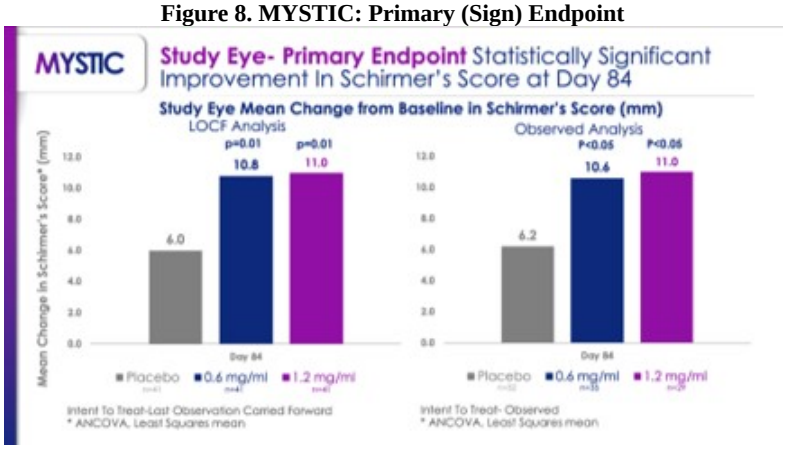
The MYSTIC study was a randomized, single-masked, vehicle-controlled Phase 2 clinical trial that evaluated the safety and efficacy of OC-01 in 123 subjects with Dry Eye Disease at the Asociación para Evitar la Ceguera (APEC) in Mexico City. APEC is the largest specialized ophthalmology hospital in North America by patient volume. The study compared two different doses of OC-01 nasal spray (0.6 mg/ml or 1.2 mg/ml) to vehicle control nasal spray (1:1:1 randomization). The goal of this study was to assess the safety and efficacy of twice daily dosing of OC-01 nasal spray administered for 84 days. The pre-specified primary endpoint was the assessment of tear production as measured by mean change in Schirmer's score at Day 84 as compared to vehicle control. The study design is included below:

Figure 7. MYSTIC Study Design



As shown in Figure 8, a statistically significant improvement in Schirmer's Score at Day 84 was observed in both doses as compared to placebo. The 0.6 mg/ml dose was associated with a least squares (LS) mean change from baseline Schirmer's Score of 10.6 mm (95% CI 7.9-14.0; $p<0.05$), while the 1.2 mg/ml dose was associated with a least squares (LS) mean change from baseline Schirmer's Score of 11.0 mm (95% CI 7.9-13.4; $p<0.05$). Results were statistically significant in both the observed and Last Observation Carried Forward analyses.

Figure 8. MYSTIC: Primary (Sign) Endpoint



OC-01 was well tolerated at all doses assessed in the study with no serious adverse events reported suspected to be related to the study drug. The most commonly reported drug-related adverse events in MYSTIC were non-ocular, whereas reports of ocular adverse events were few and transient. The number of subjects reporting non-ocular treatment-emergent adverse event (TEAE) in any dose group was 6 out of 41 (14.6%) in each OC-01 nasal spray dose groups and 9 out of 41 (22.0%) in the vehicle control group. There were no reports of serious TEAE in the study and no serious adverse events related to study drug administration. The most common overall adverse events in the nasal spray groups were blurry vision, sneezing, and headache. All events were mild in the OC-01 nasal spray groups and resolved by the next visit.

Figure 9. MYSTIC: Non-Ocular Adverse Events Occurring in More than One Subject in any Treatment Group

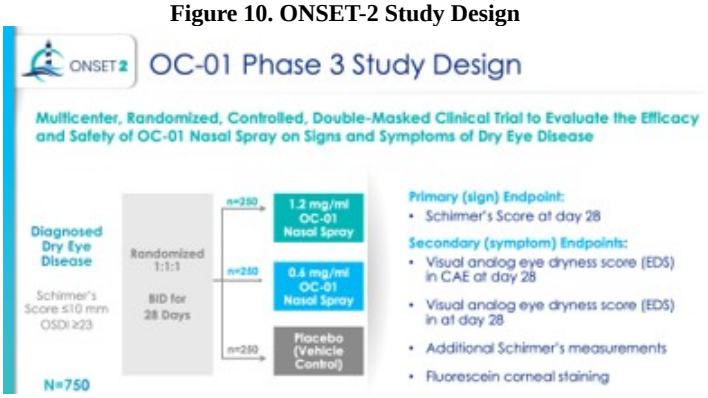
System Organ Class (1) High level Term Preferred Term	OC-01 0.6 mg/ml (n=41) n (%)	OC-01 1.2 mg/ml (n=41) n (%)	Placebo n=41 n (%)
Subjects with Non-Ocular Adverse Events	6 (14.6)	6 (14.6)	9 (22.0)
Nervous System Disorders			
Headache	2 (4.9)	2 (4.9)	0
Respiratory			
Sneeze after any instillation	2 (4.9)	3 (7.3)	2 (4.9)
Throat irritation after any instillation	2 (4.9)	0	0
Nosebleed	0	0	2 (4.9)
Gastrointestinal Disorders			
Nausea	0	1 (2.4)	2 (4.9)

(1)Column header counts and denominators are the number of treated subjects. Subjects are counted at most once within each Medical Dictionary for Regulatory Activities system organ class and preferred term row.

ONSET-2: Phase 3 clinical trial

ONSET-2 is a multicenter, dose-ranging, randomized, double-masked, placebo (vehicle)-controlled, Phase 3 clinical trial that evaluated the safety and efficacy of OC-01 in approximately 750 subjects with DED in the United States The study design is included below:

Figure 10. ONSET-2 Study Design



We expect to report top-line results from this second registrational trial by the end of the second quarter 2020.

Regulatory

We met with the FDA in February 2019 for an end of Phase 2 meeting following the completion of ONSET-1, and the FDA indicated that ONSET-1 could serve as one of the two pivotal safety and efficacy studies required to support a 505(b)(2) NDA filing for OC-01. Based on this feedback, we initiated ONSET-2, a 750-subject, multicenter, randomized, double-masked, placebo-controlled Phase 3 trial, in July 2019. The objective of this study is to evaluate the safety and efficacy of OC-01 at 0.6 mg/ml and 1.2 mg/ml doses as compared to placebo on signs and symptoms of DED. Assuming the effect size seen in ONSET-1, and based on this sample size, the power for each dose for both sign and symptom endpoints would be 99% or greater. This study, in addition to ONSET-1, allows us to achieve the minimum number of subjects for safety-monitoring purposes. This study has similar eligibility criteria and design to ONSET-1.

We met with the FDA again in July 2019 for another end of Phase 2 meeting focused on Chemistry, Manufacturing, and Controls (CMC) with regard to OC-01. The purpose of this meeting was to discuss with the FDA our proposed manufacturing plan that included stability testing, microbiology testing, and the size of our drug product registration batches to support NDA submission. We will continue to engage with the FDA in an ongoing fashion on manufacturing topics as we move toward commercialization of OC-01.

Developing OC-01 for additional indications associated with and beyond DED

Leveraging our nAChR domain expertise, we continue to explore the development of OC-01 for a number of potential indications and uses associated with and beyond DED including neurotrophic keratitis, dry eye associated with contact lens intolerance, and ocular surface treatment for refractive surgeries.

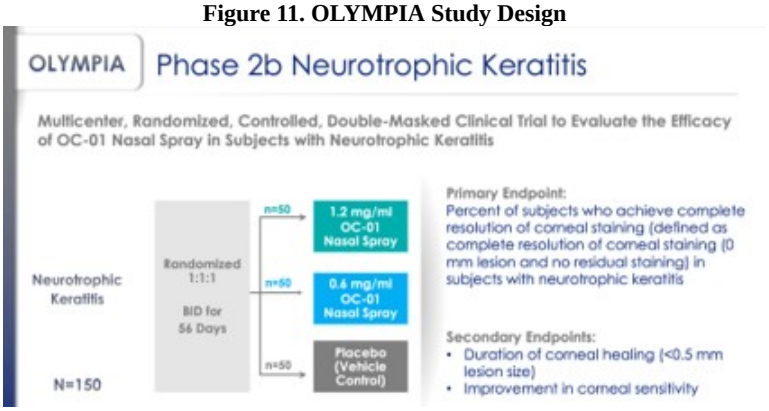
Neurotrophic keratitis

Neurotrophic keratitis (NK) is caused when the nerves that supply the cornea cannot function properly. NK reduces sensitivity of the cornea. When the cornea senses stimulation or pressure, the eyelids will close and tears will be produced to protect the cornea and the eye. Because these nerves do not function properly in NK, the outer layer of the cornea, called the epithelium, can break down, resulting in an epithelial defect. In more advanced NK, an interior layer called the cornea stroma can break down as well, resulting in thinning of the cornea. This is called stromal "melting." In advanced stromal melting, the cornea can thin to a severe degree, which can result in a hole or opening to the inside of the eye, which can lead to infection and potentially loss of the eye. NK can lead to a variety of complications, including poor wound healing of the cornea, scarring of the cornea, and loss of vision. There are many different conditions that can damage the nerves serving the cornea.

A variety of therapies can be used to treat this disorder depending on how far the disorder has progressed in an individual. Most recently, Oxervate, a recombinant human nerve growth factor, has been approved for the treatment of NK. Unfortunately there are several limitations to this therapy, including that the product must be refrigerated, administered six times per day at two-hour intervals for eight weeks, and delivered with a pipette that can be cumbersome for self-administration. Additionally, the cost of the product is more than $90,000 for an eight-week course of therapy.

Normal tear film contains a number of biologically active growth factors including nerve growth factor, epidermal growth factor, transforming growth factor-beta, hepatocyte growth factor, platelet-derived growth factor, vascular endothelial growth factor, fibroblast growth factor, keratinocyte growth factor, and insulin-like growth factor. We believe that stimulating natural tear film production twice daily for eight weeks may provide appropriate nourishment and lubrication that will be beneficial in treating NK. The study design is included below:

Figure 11. OLYMPIA Study Design



Preclinical data for OC-01

As varenicline was previously studied by Pfizer in support of the approval of NDA 21-928 for Chantix, the appropriate preclinical studies including toxicology studies in rats, dogs, mice, and monkeys with duration of single dose to 12 months, two-year carcinogenicity studies in mice and rats, standard battery of genotoxicity studies, reproductive toxicity studies in rats and rabbits, and special toxicology studies were performed.

OC-01 pharmacodynamic assessment

We conducted a non-GLP pilot study to examine the agonist effects of OC-01 at human neuronal nAChRs subtypes by utilizing *Xenopus* oocytes, overexpressing human α3ß4, α3α5ß4, α4ß2, α4α6ß2 and α7 receptors, and a two-electrode voltage clamp design. Determination of the agonistic effects of OC-01 at the human α3ß4, α3α5ß4, α4ß2, α4α6ß2 and α7 nAChRs revealed that OC-01 has full agonist activity at the α7 receptor and partial agonist activity at the α3ß4, α3α5ß4, α4ß2, and α4α6ß2 receptors.

OC-01 toxicology studies

In support of the approval of NDA 21-928, a number of preclinical studies including toxicology studies in rats, dogs, mice, and monkeys with duration of single dose to 12 months, two-year carcinogenicity studies in mice and rats, standard battery of genotoxicity studies, reproductive toxicity studies in rats and rabbits, and special toxicology studies were performed by Pfizer. We have also conducted repeat-dose toxicity studies of OC-01 in rats and rabbits for up to 28 days and a 26-week study in Dutch Belted rabbits is ongoing. This section includes a summary of the preclinical experience with varenicline to date, although it is not an exhaustive review of all studies performed to support the approval of varenicline.

Repeat-dose, seven-day GLP toxicology studies of OC-01 administered three times daily by intranasal instillation to Sprague-Dawley rats did not result in any mortality, adverse clinical signs, macroscopic findings or microscopic findings in the nasal cavity or nasopharynx. Based on these results, the no observed adverse effect level (NOAEL) was considered to be 3.6 mg/day.

Repeat-dose, seven-day GLP toxicology studies of OC-01 in Dutch Belted Rabbits did not result in any mortality, adverse clinical signs, macroscopic findings or microscopic findings in the nasal cavity or nasopharynx when given three times daily by intranasal instillation to Dutch Belted rabbits at doses up to 12.0 mg/day. Based on these results, the NOAEL was considered to be 12.0 mg/day.

Repeat-dose, 28-day GLP toxicology studies of OC-01 administered twice daily by intranasal instillation to Sprague-Dawley rats did not result in any mortality, and no OC-01-related adverse clinical signs or changes in bodyweight, food consumption, ophthalmology, electroretinography (ERGs) and functional observational battery (FOBs) were observed during the study. Administration of OC-01 three times daily for 28 days by intranasal instillation was well tolerated in the rats at levels up to 0.9 mg/day for the males and 0.18 mg/day for the females. Repeat-dose, 28-day GLP toxicology studies of OC-01 did not result in any changes to mortality, clinical signs, body weight, food consumption, nasal assessment, ophthalmology (including ERG and intraocular pressure), Schirmer's Score, clinical pathology, gross pathology, and histopathology when given two times daily by intranasal instillation to Dutch Belted rabbits at doses up to 8.0 mg/day. Based on these results, the NOAEL was considered to be 8.0 mg/day.

A repeat-dose, six-month GLP toxicology study in Dutch Belted rabbits completed in 2019 evaluated the potential toxicity of OC-01 when administered twice daily at doses up to 8.0 mg/day with a full report to be provided first half of 2020.

Figure 12. Completed Intranasal GLP Toxicology Studies with OC-01 (varenicline) Nasal Spray

NON-PIVOTAL STUDIES

Study Type	Species and Strain	Duration of Dosing
Repeat-dose tox	Sprague-Dawley Rat	7 days
Repeat-dose tox	Dutch Belted Rabbit	7 days

PIVOTAL STUDIES

Study Type	Species and Strain	Duration of Dosing
Repeat-dose tox with 2-week recovery	Sprague-Dawley Rat	28 days
Repeat-dose tox with 2-week recovery	Dutch Belted Rabbit	28 days
Repeat-dose tox with 1-month recovery	Dutch Belted Rabbit	6 months

OC-02 (simpinicline)

We are also developing a second nAChR agonist product candidate OC-02 (simpinicline), which has the ability to activate the parasympathetic nervous system in a similar fashion to OC-01. OC-02 shows full agonist activity at the α3ß4, α3α5ß4, α4ß2, and α4α6ß2 receptors and weak agonist activity at the α7 receptor. We have studied OC-02 in two Phase 2b clinical trials (PEARL and RAINIER) for DED. Despite positive efficacy and safety results demonstrated in both trials, we selected OC-01 as our lead product candidate for DED due to its favorable clinical profile, the potential to leverage the 505(b)(2) regulatory pathway and significantly lower cost of development. We do not currently intend to pursue FDA approval for OC-02 in DED. However, we believe that the strong clinical data from both OC-01 and OC-02 validates this class of receptors and our mechanism of action. We believe that targeting the parasympathetic nervous system through the use of locally administered cholinergic agonists has the potential to treat a wide range of diseases and disorders. We have identified several indications other than DED where we believe

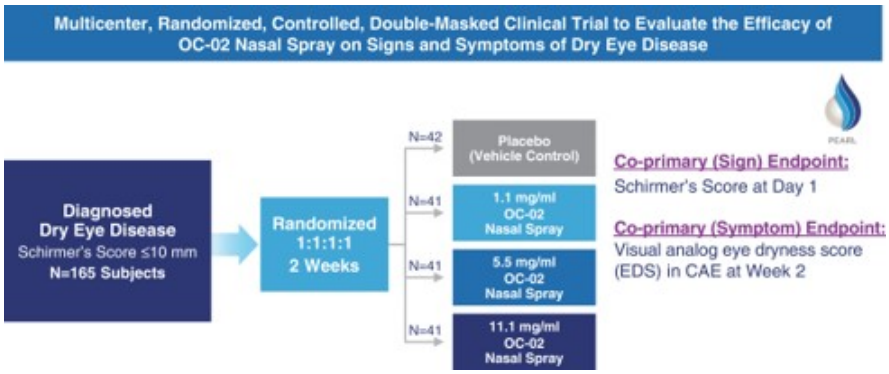
OC-02 could provide a meaningful benefit to patients. In certain indications, we believe OC-02 could advance directly into a Phase 2 proof of concept study, supported by the preclinical and clinical data that we and others have generated in DED as well as other systemic indications. However, we cannot guarantee that the FDA will permit us to advance OC-02 into a Phase 2 proof of concept study nor can we guarantee that the FDA will grant marketing approval to OC-02 for the treatment of any indication.

Our development program for OC-02

PEARL: Phase 2b clinical trial results

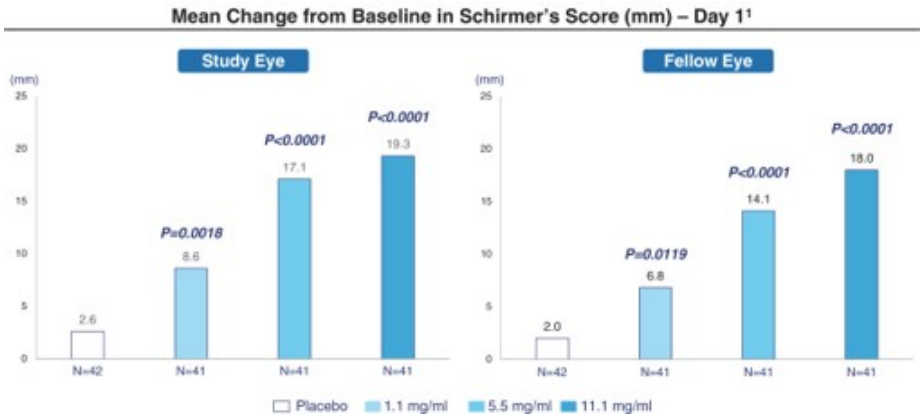
In July 2018, we reported results from PEARL, a multicenter, dose-ranging, randomized, double-masked, placebo-controlled Phase 2b clinical trial that evaluated the efficacy and preliminary safety of OC-02 in 165 patients with DED in the United States. The study compared three different doses of OC-02 to placebo. The first pre-specified co-primary (sign) endpoint was the assessment of tear production as measured by Schirmer's Score at Day 1 and the second pre-specified co-primary (symptom) endpoint was patient-reported symptoms of DED as measured by EDS in the CAE at Week 2. The study design is included below:

Figure 13. PEARL Study Design



The PEARL study was important in validating that an nAChR agonist delivered as a nasal spray could improve the signs and symptoms of DED, endpoints that had not been previously achieved in a single clinical trial by currently marketed therapies in their respective development programs. As shown in Figure 14, a statistically significant improvement in Schirmer's Score was observed at Day 1 in all three doses compared to the vehicle-controlled placebo. The 1.1 mg/ml dose group was associated with a mean change in Schirmer's Score of 8.6 mm (p=0.0018). A mean change in Schirmer's Score of 17.1 mm (p<0.0001) was observed in the 5.5 mg/ml treatment group. A mean change in Schirmer's Score of 19.3 mm (p<0.0001) was observed in the 11.1 mg/ml treatment group. The mean change in Schirmer's Score in the control arm was observed to be 2.6 mm. Also shown in Figure 14, fellow eye results were similar.

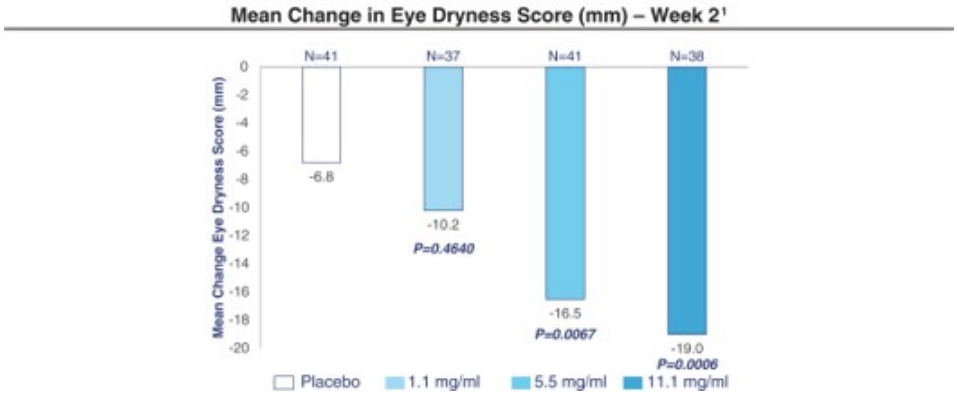
Figure 14. PEARL: Co-Primary (Sign) Endpoint



[1] ANCOVA primary analysis. ITT-observed population.

Although the low dose of 1.1 mg/ml of OC-02 was associated with a statistically significant improvement in anesthetized Schirmer's Score, it did not yield a statistically significant difference in the symptom endpoint of EDS (p=0.4640) as shown in Figure 15. A mean change in EDS of -16.5 mm was observed in the 5.5 ml/mg dose group (p=0.0067). A mean change in EDS of -19.0 mm was observed in the 11.1 mg/ml dose group (p=0.0006). The control arm had a mean change in EDS of -6.8 mm.

Figure 15. PEARL: Co-Primary (Symptom) Endpoint



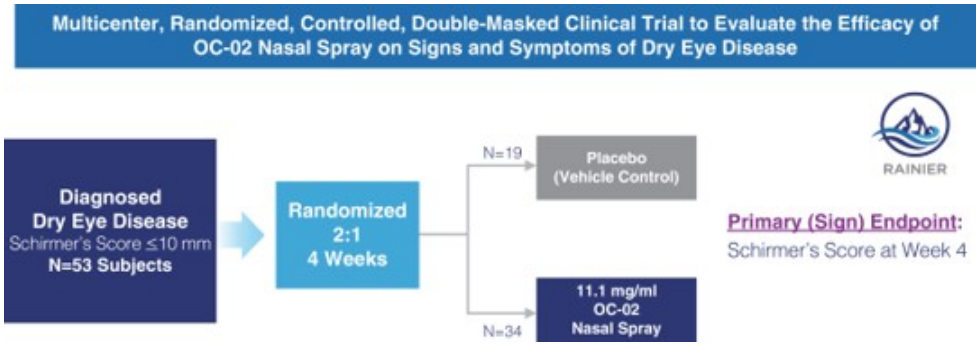
[1] ANCOVA primary analysis ITT-observed population

OC-02 was observed to be well tolerated at all doses assessed in the study. Only one serious adverse event was reported and determined to be unrelated to the study drug. The most common adverse events were typical of nasal sprays (cough, throat irritation, sneezing) and were predominantly mild, transient and self-limiting.

RAINIER: Phase 2b clinical trial results

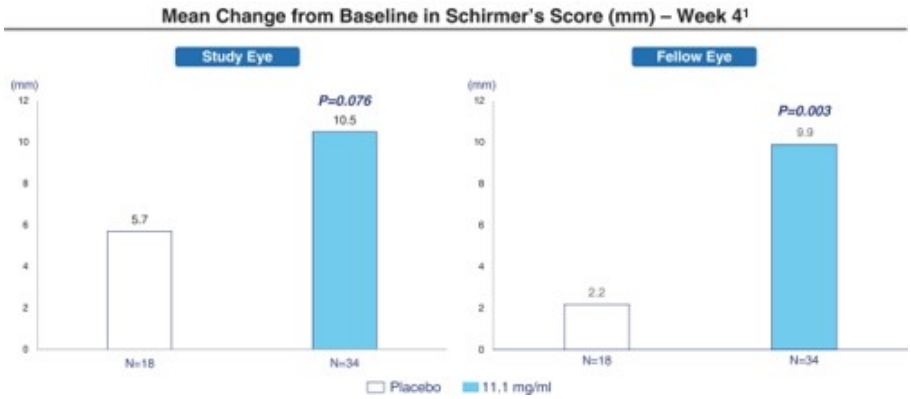
In October 2018, we reported results from RAINIER, a multicenter, randomized, double-masked, placebo-controlled, Phase 2b clinical trial that evaluated the safety and efficacy of 11.1 mg/ml OC-02 in 53 subjects with DED in the United States. At the time of the study, the sample size was limited by the amount of available OC-02. The study design is included below:

Figure 16. RAINIER Study Design



The study's sole pre-specified endpoint was the assessment of tear production as measured by anesthetized Schirmer's Score at Week 4. As shown in Figure 17, although the results were not statistically significant for the pre-specified endpoint, OC-02 was associated with an increase in tear film production as measured by an improvement in Schirmer's Score in the study eye at Week 4 compared to the vehicle-controlled placebo. The OC-02 treatment group had a mean change in Schirmer's Score of 10.5 mm (p=0.076). The vehicle-controlled placebo treatment group had a mean change in anesthetized Schirmer's Score of 5.7 mm. Also shown in Figure 17, the anesthetized Schirmer's Score results were statistically significant in the fellow eyes of subjects (p=0.003).

Figure 17. RAINIER: Primary (Sign) Endpoint



[1] ANCOVA, Least Squares mean. ITT-observed population.

OC-02 was observed to be well tolerated at the 11.1 mg/ml dose assessed in the study. The most common adverse event in all treatment groups was sneezing, which was temporally related to the administration of the study drug and resolved soon after administration. Sneezing adverse events were characterized as mild to moderate, with no severe adverse events reported.

Preclinical data for OC-02

OC-02 pharmacodynamic assessment

A non-GLP pilot study was conducted to examine the agonist effects of OC-02 at human neuronal nAChRs subtypes by utilizing Xenopus oocytes, overexpressing human α3ß4, α3α5ß4, α4ß2, α4α6ß2 and α7 receptors with a two-electrode voltage clamp design. OC-02 was shown to be a weak agonist at the α7 receptors, evoking only 24% of the maximal acetylcholine (Ach)-evoked current at the highest dose tested. In contrast, OC-02 evoked two times the maximal Ach-evoked current at the highest dose tested at the α4ß2 receptor. Moreover, at the α3ß4 and at α3α5ß4 receptors, OC-02 was shown to evoke approximately 94% of the maximal ACh-evoked currents. OC-02 was shown to have full agonist activity at the α3ß4, α3α5ß4, α4ß2, and α4α6ß2 receptors and weak agonist activity at the α7 receptor.

OC-02 toxicology studies

Single-dose administration of the 5% dose of OC-02 in New Zealand White rabbits did not result in any test substance-related clinical observations, skin reactions inside or outside the nose, nasal reactions, gross observations at necropsy or histopathological effects for the seven-day evaluation period.

Repeat-dose, seven-day GLP toxicology studies of OC-02 did not result in any mortality, adverse clinical signs, macroscopic findings or microscopic findings in the nasal cavity or nasopharynx when given three times daily by intranasal instillation to Sprague-Dawley rats. Based on these results, the NOAEL was considered to be 6%. Repeat-dose, seven-day GLP toxicology studies of OC-02 did not result in any mortality, adverse clinical signs, macroscopic findings or microscopic findings in the nasal cavity or nasopharynx when given three times daily by intranasal instillation to New Zealand White rabbits. Based on these results, the NOAEL was considered to be 6%.

In repeat-dose, 28-day GLP toxicology studies, OC-02 was administered three times daily in Sprague-Dawley rats. There were no related adverse clinical signs or changes in bodyweight, food consumption, ophthalmology, ERGs and FOBs determined to be OC-02 related. Administration of OC-02 three times daily for 28 days by intranasal instillation was well tolerated in rats at levels up to 6%. Repeat-dose, 28-day GLP toxicology studies of OC-02 did not result in any changes to mortality, clinical signs, body weight, food consumption, nasal assessment, ophthalmology (including ERG and intraocular pressure), Schirmer's Score, clinical pathology, gross pathology, and histopathology when given three times daily by intranasal instillation to Dutch Belted rabbits at doses up to 8.0 mg/day. Based on these results, the NOAEL was considered to be 6%.

A repeat dose, six-month GLP toxicology study in Sprague-Dawley rats completed in 2019 evaluated the potential toxicity of OC-02 when administered twice daily at doses up to 3.98 mg/day. A repeat dose, nine-month GLP toxicology study in New Zealand White rabbits completed in 2019 evaluated the potential toxicity of OC-02 when administered twice daily at doses up to 13.28 mg/day. A full report will be available in the first half of 2020.

Figure 18. Completed Intranasal Toxicology Studies with OC-02 (simpinicline) Nasal Spray

NON-PIVOTAL STUDIES

Study Type	Species and Strain	Duration of Dosing
Single Dose Toxicity	New Zealand White Rabbit	1 day
Repeat-dose tox	Sprague-Dawley Rat	7 days
Repeat-dose tox	New Zealand White Rabbit	7 days

PIVOTAL STUDIES

Study Type	Species and Strain	Duration of Dosing
Repeat-dose tox with 2-week recovery	Sprague-Dawley Rat	28 days
Repeat-dose tox with 2-week recovery	New Zealand White Rabbit	28 days
Repeat-dose tox with 1-month recovery	Sprague-Dawley Rat	6 months
Repeat-dose tox with 1-month recovery	Dutch Belted Rabbits	9 months

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 currently approved therapies 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.

A number of therapies are currently available for the treatment of DED in the United States. The most commonly used treatments for DED in the United States are over-the-counter eye drops, often referred to as “artificial tears,” and three FDA-approved prescription eye drop therapies: Restasis, Xiidra and Cequa. Artificial tears are intended to supplement insufficient tear production or improve tear film instability, but are primarily saline-based and provide only temporary relief. Restasis and Cequa, both calcineurin inhibitor immunosuppressants, and Xiidra, a LFA-1 antagonist, address chronic inflammation associated with DED. Other treatment options include ointments, gels, warm compresses, omega-3 fatty acid supplements and a number of medical devices. We are aware of many other companies developing therapies for DED, including Aerie Pharmaceuticals, Alcon, Aldeyra Therapeutics, Allergan, Aurinia Pharmaceuticals, Azura Ophthalmics, Bausch Health (Novaliq), HanAll BioPharma, Johnson & Johnson, Kala Pharmaceuticals, Mitotech, Novartis, Parion Sciences, ReGenTree, Silk Technologies, Sylentis, TopiVert Pharma, and TearSolutions.

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 our product candidates receive marketing approval, we plan to commercialize them in the United States with a focused, specialty sales force that could consist of our own employees, outsourced sales professionals, or a hybrid model utilizing both internal and external resources. We believe that this commercial organization at the launch of OC-01 will consist of approximately 150 to 200 field sales representatives that will call on top-prescribing ophthalmologists and optometrists. We believe an organization of this size would allow us to reach ECPs that collectively care for more than 80% of patients diagnosed with DED in the United States. Given the importance of increasing awareness and educating patients with DED, we also anticipate deploying focused direct-to-consumer marketing campaigns for OC-01. We anticipate that our sales force could also support the commercialization of additional product candidates treating ocular diseases. We would expect to conduct most of the buildout of this organization following NDA approval of our product candidates. We expect to explore commercialization of OC-01 and potentially other

product candidates in certain markets outside the United States, including the European Union, utilizing a variety of collaboration, distribution and other marketing arrangements with one or more third parties.

Manufacturing

We do not currently own or operate facilities for manufacturing, storing, distributing or testing our product candidates. We rely, and expect to continue to rely for the foreseeable future, on third-party contract manufacturing organizations (CMOs), to manufacture and supply our preclinical and clinical materials to be used during the development of our product candidates.

The product candidate OC-01 is a presentation of varenicline, the API, formulated into a nasal spray formulation comprised of phosphate buffer to provide appropriate pH control and sodium chloride to obtain suitable osmolality for a nasal spray. We believe the amounts of the API as well as OC-01 we currently have on hand are sufficient to complete ONSET-2 and ZEN. Additional cGMP API campaigns for varenicline are in process to ensure full supply for our commercial scale-up, validation and commercial launch activities if OC-01 is approved.

The product candidate OC-02 is a presentation of simpinicline, the API, formulated into a nasal spray formulation comprised of phosphate buffer to provide appropriate pH control and sodium chloride to obtain suitable osmolality for a nasal spray. We believe that we will be able to continue to obtain the OC-02 API on commercially reasonable terms for any future clinical trials.

Although we currently rely on separate, single CMOs as our sole suppliers for both the non-clinical and clinical supply for the OC-01 API and OC-02 API under cGMP protocols and a single CMO to manufacture OC-01 and OC-02 and to perform analytical testing services, it is our intent to identify and qualify additional manufacturers to provide OC-01 API and drug product manufacturing and analytical testing services, if possible, prior to submission of the NDA for OC-01. We expect that we can easily find additional OC-01 API manufacturers as the OC-01 API is a small molecule currently being manufactured by a number of suppliers throughout the world. Additionally, the drug product manufacturing is a simple compounding and aseptic filling operation that could also be transferred to additional CMOs as necessary.

Our third-party service providers, our third-party supply chain providers, their facilities and the OC-01 and OC-02 used in our clinical trials or for commercial sale are required to be in compliance with current Good Manufacturing Practices (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 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 OC-01 and OC-02 to assess compliance with applicable regulations. Our failure, or the failure to 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 OC-01 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.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. Our patent portfolio is intended to cover our product candidates and components thereof, their methods of use and processes for their manufacture, our proprietary reagents and assays and any other inventions that are commercially important to our business. We also rely on trade secret protection of our confidential information and know-how relating to our proprietary technology, platforms and product candidates.

Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the U.S. Patent and Trademark Office (USPTO) in examining the patent application (patent term adjustment, or PTA) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension, or PTE), or both. In addition, we cannot provide any assurance that any

patents will be issued from our pending or future applications or that any issued patents will adequately protect our products or product candidates.

Our patent portfolio as of December 31, 2019 contains approximately 15 issued and unexpired U.S. patents, six pending U.S. patent applications, and two pending patent cooperation treaty (PCT) applications that are solely owned by us and certain foreign counterparts of a subset of these patents and patent applications in foreign countries, including Australia, Brazil, Canada, China, Japan, South Korea, Mexico, and countries within the European Patent Convention and the Eurasian Patent Organization. Owing to the substantial cost of prosecuting patent application internationally, we have selectively and strategically abandoned certain of our patent applications in countries with smaller markets and/or a history of weak patent enforcement record. With respect to our candidate OC-01, our patents and patent applications include methods of treatment. With respect to our candidate OC-02, our patents and patent applications cover chemical composition, synthesis and preparation, formulations, and methods of treatment. We continue to seek to maximize the scope of our patent protection for all our programs. We have five issued U.S. patents relating to methods of treating dry eye disease, increasing tear production, and improving ocular discomfort using varenicline, as well as pharmaceutical formulations for local nasal administration of varenicline. The patents are U.S. Pat. Nos.: 9,504,644, 9,504,645, 9,532,944, 9,597,284 and 10,456,396. These patents expire in 2035.

In October 2016, we purchased simpinicline, the compound we refer to as OC-02 and all of the intellectual property rights in and to such compound, including the related know-how and patents, pursuant to an asset purchase agreement, which was subsequently amended in November 2016 and May 2017 (as amended, the OC-02 Agreement). Under the OC-02 Agreement we are obligated to make milestone payments of up to an aggregate of $37.0 million upon achievement of certain development and regulatory milestone events. In March 2018, we made a payment of $1.5 million upon completion of the first of these milestones. The next milestone payment is payable on the first dosing of a patient in a Phase 3 clinical trial of OC-02. Under the OC-02 Agreement, we are also obligated to make royalty payments at a mid-single digit percentage rates on net worldwide sales of the covered products. In addition, we are required to pay 15% of any (i) licensing revenue we receive that is related to OC-02 and (ii) revenue received from the sale of OC-02, up to a maximum aggregate amount of $10.0 million. We do not currently receive any licensing or sales revenue for OC-02.

We believe that we have certain know-how and trade secrets relating to our technology and product candidates. We rely on trade secrets to protect certain aspects of our technology related to our current and future product candidates. However, trade secrets can be difficult to protect. We seek to protect our trade secrets, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, service providers, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Licenses

On October 18, 2019, we entered into a non-exclusive patent license agreement (the License Agreement) with Pfizer. Pursuant to the License Agreement, Pfizer granted us non-exclusive rights under Pfizer's patent rights covering varenicline tartrate and related salts thereof, including U.S. Patent Nos.: 7,265,119 and 6,890,927 to develop, manufacture, and commercialize our OC-01 varenicline product candidate for the treatment of any ophthalmic disease or condition via nasal administration in the United States.

Under the terms of the agreement, we made an upfront payment to Pfizer of $5.0 million. If we successfully commercialize OC-01, we may be required to pay to Pfizer a single milestone payment in the very low double-digit millions if we achieve a specified level of annual aggregate net sales of OC-01 within a specified timeframe. We will also be required to pay Pfizer tiered royalties on net sales of OC-01 by us, our affiliates, or sublicensees, at percentages ranging from the mid-single digits to the mid-teens. Our royalty obligation to Pfizer will commence upon first commercial sale of OC-01 and will expire upon the later of (a) the expiration of all regulatory or data exclusivity granted to Pfizer in connection with varenicline in the United States; and (b) the expiration or abandonment of the last valid claims of the licensed patents.

The License Agreement will terminate when all claims in all the licensed patents expire or are irretrievably abandoned, which we expect to be no later than August 2022. The License Agreement may be terminated earlier by us for any reason, or by Pfizer upon 60 days' written notice for our uncured material breach (30 days in the case of non-payment), or immediately upon our insolvency.

Regulatory Pathway

Varenicline tartrate is currently marketed by Pfizer in the United States under the trade name Chantix as an aid to smoking cessation treatment. We have filed an Investigational New Drug Application (IND) with the FDA to study varenicline for the

treatment of the signs and symptoms of dry eye disease and intend to submit a 505(b)(2) NDA, relying in part upon certain FDA conclusions regarding the safety of varenicline from the Agency's review of the Chantix NDA.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries 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. 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.

U.S. Drug Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (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. requirements at any time during the product development process, approval process or post-marketing may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or 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 (GLP) requirements;
- submission to the FDA of an investigational new drug application (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 institutional review board (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, good clinical practice (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 filing 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 current good manufacturing practice (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 Risk Evaluation and Mitigation Strategy (REMS), and the potential requirement to conduct post-approval studies.

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

Preclinical Studies and IND Submission

Before testing any drug product candidate in humans, the product candidate must undergo rigorous preclinical testing. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for 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, 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 submit data from the clinical trial to the FDA in support of an NDA. The FDA will 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 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. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check-points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal safety studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of our product candidates. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that our product candidates do not undergo unacceptable deterioration over their labeled shelf life.

NDA Review

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 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 (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 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 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 to twelve months, whereas the FDA's goal is to review priority review applications within six to eight 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.

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

Section 505(b)(2) New Drug Applications

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy conducted by or on behalf of the applicant. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations, new routes of administration, or new uses of previously approved products. If the Section 505(b)(2) applicant can establish that reliance on the FDA's prior findings of safety and/or effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's prior findings of safety or effectiveness for an already approved product, the applicant is required to provide a certification to the FDA concerning each patent listed for the approved product in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book). Depending on the type of certification, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, listed in the Orange Book for the reference product, such as the 5 years of exclusivity for obtaining approval of a new chemical entity has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit brought by the holder of the listed patent, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

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 adverse event and other periodic reporting, product sampling and distribution, and product promotion and advertising including restrictions on promoting

drugs for unapproved uses or patient populations, known as “off-label use,” and limitations on industry-sponsored scientific and educational activities. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

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. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

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. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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

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

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Other Regulatory Matters

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. 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 that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- 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;

- the federal Physician Payments Sunshine Act 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 payments and other transfers of value to physicians and teaching hospitals 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 biotechnology companies to comply with the biotechnology 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 biotechnology companies 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.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

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

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

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The 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 (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 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 (NCA) and one or more Ethics Committees (ECs). 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 the European Economic Area (EEA), which is comprised of the 27 Member States of the European Union (including Norway and excluding Croatia), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (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 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.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the European Union, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (SPC), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, EMA or the competent authorities of the Member States of the European Union make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Similar to the U.S. patent term-restoration, Supplementary Protection Certificates (SPCs) serve as an extension to a patent right in Europe for up to five years. SPCs apply to specific pharmaceutical products to offset the loss of patent protection due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

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 typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's 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.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

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 Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), 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 ACA 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 Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA 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, 2020, Medicaid rebate liability will be expanded to include the territories of the United States as well. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have passed. 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 ACA 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 January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case to the District Court to determine whether the remaining provisions of the ACA are invalid. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA 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 2027 unless additional Congressional action is taken. 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. These 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 recently 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 released a “Blueprint” to lower prescription drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. Additionally, on January 31, 2019, HHS Office of Inspector General (OIG) issued proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufactures to Medicare Part D plan sponsors, Medicaid managed care organizations, and those entities’ pharmacy benefit managers, the purpose of which is to further reduce the cost of drug products to consumers. 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 (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.

Research and Development

We recognized $33.6 million and $13.8 million of research and development expenses in the years ended December 31, 2019 and 2018, respectively.

Financial Information about Segments

We operate and manage our business as one reportable operating segment. Our Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. See "Note 1- Organization and Summary of Significant Accounting Policies" in the notes to the financial statements included elsewhere in this Annual Report on Form 10-K.

Employees

As of December 31, 2019, we had 30 full-time employees, 17 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.

Corporate Information

We were incorporated in Delaware in June 2015. We were spun out from Oculeve, Inc., a Delaware corporation focused on the treatment of dry eye disease, prior to its acquisition by Allergan. Our principal executive offices are located at 202 Carnegie Center, Suite 109, Princeton, New Jersey 08540. Our telephone number is (609) 382-9032. Our website address is www.oysterpointrx.com. We also use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD.

We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We make available on our website at www.oysterpointrx.com, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov. The information in or accessible through the SEC and our website or social media sites does not constitute part of this Annual Report on Form 10-K or any other report or document we file with the SEC, and any references to our website and social media sites are intended to be inactive textual references only.

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

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report on Form 10-K and in other documents that we have filed and will file with the SEC, in evaluating our company and our business. Additional risks and uncertainties not presently known to us or that we currently see as immaterial may also harm our business. If any of these risks occur, our business, growth prospects, operating results and financial condition could be materially and adversely affected, the trading price of our common stock could decline and you could lose part or all of your investment.

Risks Related to Our Business

We are a clinical stage biopharmaceutical company with limited operating history. We have incurred significant losses and negative cash flows from operations since our formation, and we anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical stage biopharmaceutical company with a limited operating history. Our operations to date have been limited to organizing our company, raising capital and developing our product candidates. 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. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a clinical development focus to a company capable of supporting commercial activities. We have not yet demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization, and we may not be successful in such a transition.

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. We have funded our operations primarily from the sale and issuance of our securities. Our net losses were $45.7 million and $16.5 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $84.2 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 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:

- initiate additional preclinical, clinical and other studies for our product candidates or expand or modify existing studies or currently planned studies;
- 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 and our product development and planned future commercialization efforts;
- 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 and develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments in connection with the development or approval of our product candidates;
- maintain, protect, and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

We are highly dependent on the success of our lead product candidate OC-01 for the treatment of dry eye disease. If we are unable to successfully complete our clinical development program for OC-01 and obtain the marketing approvals necessary to commercialize OC-01 or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize this product candidate, our business will be materially harmed.

We have devoted a significant portion of our financial resources and business efforts to the development of OC-01 for the treatment of dry eye disease (DED). Although we are also developing OC-01 for other indications and a second product candidate OC-02, we do not anticipate receiving marketing approvals for any product candidates other than OC-01 in the next several years. Our ability to generate revenues from product sales will depend on our obtaining marketing approval for and commercializing OC-01, and we cannot accurately predict when or if OC-01 will be proven to be effective or safe in humans or whether it will receive marketing approval for DED or a secondary indication. Because we have focused our resources and efforts on developing OC-01 for DED, we have limited resources and may fail to commit adequate resources to, or delay the pursuit of opportunities for, other indications or other product candidates that may have greater commercial potential, and our resource allocation decisions may cause us to fail to capitalize on viable product candidates and profitable market opportunities. If we fail to successfully develop OC-01 for DED, we may not be able to identify, assess and develop OC-01 for other indications or OC-02 or a second lead product candidate or other product candidates on a timely basis, which could materially affect our business, financial condition, results of operations and growth prospects.

Our business depends entirely on the successful discovery, development and commercialization of OC-01, OC-02 and other future product candidates. 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 until either OC-01 or another product candidate receives the regulatory and marketing approvals necessary for commercialization. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any future collaborator's ability, to achieve a number of objectives, including:

- successful and timely completion of preclinical and clinical development of our product candidates, including OC-01, OC-02 and any other future product candidates;

- establishing and maintaining relationships with contract research organizations (CROs) and clinical sites for the clinical development, both in the United States and internationally, of our product candidates, including OC-01, OC-02 and any other future product candidates;

- timely receipt of marketing approvals from applicable regulatory authorities for any 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;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile both prior to and following any marketing approval of our product candidates;
- commercial acceptance of our 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 by hospitals, government and third-party payors for product candidates that we develop;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability, or comparable to the revenues of existing therapies, including Restasis and Xiidra. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would 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.

Our lead product candidate OC-01 is based on an active pharmaceutical ingredient (API) that is already on the market, which exposes us to additional risks.

The API in OC-01, varenicline (in the form of varenicline tartrate), has been previously approved by the FDA and the EMA as an oral tablet under the trade name Chantix, an aid to smoking cessation treatment, and is available in more than 80 countries throughout the world. From 2009 to 2016, the FDA required Chantix to carry a boxed warning advising consumers of potential serious mental health side effects from Chantix. Although the FDA removed this box warning from Chantix in 2016 in response to the EAGLES study sponsored by Pfizer, regulatory authorities may identify other adverse side effects related to varenicline in the future or may add back the warning. Additionally, we anticipate that manufacturers will begin selling varenicline in generic form in the future, which could lead to increased use of varenicline by patients and increase the possibility that patients experience adverse side effects related to varenicline. Any adverse side effects that arise from the use of any form of varenicline, whether Chantix, generic varenicline or our product candidate, or reporting thereof could prevent or inhibit the commercialization of OC-01 and seriously harm our business. Furthermore, if manufacturer demand for varenicline increases in the future, particularly as a result of generic forms of varenicline becoming available, we may not be able to continue to obtain varenicline on commercially reasonable terms, which would seriously harm our business.

OC-01 uses a novel and unproven therapeutic approach and mechanism of action to treat DED and therefore its efficacy and safety are difficult to predict, and there is no guarantee that OC-01 or any other product candidates will be approved by the FDA.

We are developing OC-01 as a preservative-free, aqueous nasal spray that will stimulate the lacrimal functional unit (LFU) to produce natural tear film. To our knowledge, OC-01 represents the first pharmacological treatment approach for DED that is aimed at stimulating the LFU. Other than with respect to data from studies and trials of OC-01 and OC-02, there is limited or no clinical evidence showing that natural tear film can be produced through the stimulation of the LFU. For instance, even though OC-01 has shown promising results in preclinical studies and prior clinical trials, we may not succeed in demonstrating safety and efficacy of OC-01 in larger-scale clinical trials, including ONSET-2, our ongoing Phase 3 clinical trial, or for other indications, including OLYMPIA, our upcoming Phase 2 clinical trial for neurotrophic keratitis (NK).

Advancing OC-01 as a novel product creates significant challenges for us, including:

- obtaining marketing approval;
- educating medical personnel, including eye care practitioners (ECPs), and patients regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating our product candidates, if approved, into treatment regimens; and
- establishing the sales and marketing capabilities upon obtaining any marketing approvals to gain market acceptance.

We cannot guarantee that OC-01 or any of our other future product candidates will be approved by the FDA. Product candidates in later-stage clinical trials often fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA and other comparable foreign regulatory authorities despite having successfully progressed through preclinical studies and other clinical trials. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. For example, although we expect to enroll a subject population with similar eligibility criteria, OC-01 may not demonstrate the same or similar statistically significant results in ONSET-2 as it demonstrated in ONSET-1, our Phase 2b clinical trial, MYSTIC, our Phase 2 long-term chronic efficacy study, ZEN, our comparative pharmacokinetic “bridge” trial, or our other clinical trials. Additionally, we cannot guarantee that the safety profile of OC-01 in healthy volunteers and patients with DED will be replicated in trials and studies for other indications, such as NK. Assessments of efficacy can vary widely for a particular participant, and from participant to participant and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. In addition, participants treated with OC-01 may also be treated with other investigational drugs, prescription drugs or even over-the-counter treatments following the treatment period of our OC-01 studies, any of which can cause side effects or adverse events that are unrelated to our product candidate, but which are observed during the long-term safety follow-up for OC-01. The occurrence of such side effects or adverse events could have a negative impact on OC-01’s safety profile.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. The outcome of preclinical testing and earlier clinical trials may not be predictive of the success of later clinical trials. The results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.

Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory, including marketing, approval, which is necessary before they can be commercialized. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Product candidates in later stages of clinical trials may fail to show the desired safety, efficacy and durability profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical and clinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of subjects may not be predictive of those obtained in another. In some instances, there can be significant variability in safety, efficacy or durability results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants.

We may also experience issues in implementing our clinical trials that would delay or prevent us from satisfying the applicable requirements of the FDA and other regulatory authorities, including:

- the number of participants required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their obligations to us in a timely manner, or at all;
- other regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; and
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites.

We may be unable to design and execute clinical trials that support marketing approval. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. For example, use of OC-01 requires the patient to follow a prescribed technique to administer the nasal spray. Failure to properly administer the nasal spray by the patient or inappropriate technique demonstration by the ECP, may adversely affect the outcome of OC-01 in demonstrating efficacy in one or more clinical trials. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could materially affect our business, financial condition, results of operations and growth prospects.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of subjects to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Any difficulties we experience relating to enrollment in ONSET-2 could delay regulatory approval for OC-01.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and subjects who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment for any of our future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- participant eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- ECPs' and participants' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;

- efforts to facilitate timely enrollment in clinical trials;
- participant referral practices of ECPs;
- the ability to monitor participants adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective trial subjects;
- continued enrollment of prospective subjects by clinical trial sites; and
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion.

Our inability to enroll a sufficient number of subjects for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of subjects for our clinical trials, we may have difficulty maintaining enrollment of such subjects in our clinical trials.

Our current or future product candidates may cause or reveal significant adverse events, toxicities or other undesirable side effects which may delay or prevent marketing approval. 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 or associated with treatment 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, EMA 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 ONSET-1, ZEN and MYSTIC were non-ocular in nature, which were sneezing and coughing. If approved, we expect that OC-01 will be used chronically over a prolonged period of time. However, we have no clinical safety data on patients treated with OC-01 for longer than 84 days and these adverse events are subjective and based on subjects' self-report, which may not accurately reflect the actual number of adverse events. 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 may occur. If additional clinical experience indicates that OC-01 or any other product candidate has side effects or causes serious or life- threatening side effects, participant recruitment for studies and the ability of enrolled subjects to complete studies could be negatively impacted, and the development of the product candidate may fail or be delayed, which would severely harm our business, growth prospects, operating results and financial condition.

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

- regulatory authorities may withdraw approvals of such product or require additional warnings on the label;
- 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 a Risk Evaluation and Mitigation Strategy (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;
- we could be sued and held liable for harm caused to patients; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could materially affect our business, financial condition, results of operations, and growth prospects.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could materially affect our business, financial condition, results of operations and growth prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize our product candidates may be harmed, which could materially affect our business, financial condition, results of operations and growth prospects.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified executives as we build out the management team, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and need to continue to add executives with operational and commercialization experience as we plan for commercialization of our product candidates and build out a leadership team that can manage our operations as a public company. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

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

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

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

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

We expect to significantly expand our organization, including building sales and marketing capability and creating additional infrastructure to support our operations as a public company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing and finance and accounting. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert or stretch our management and business development resources in a way that we may not anticipate. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our business and operations would suffer in the event of security breaches, system failures and other disruptions.

Despite the implementation of security measures, our computer systems, as well as those of our contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. The application and data we possess contain critical information, including research and development information, commercial information, personal information about our employees and consultants, and business and financial information. Protecting this critical information includes risks, including loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of being unable to adequately monitor our internal controls to prevent security breaches, system failures and other cybersecurity disruptions.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

The secure processing, storage, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the

information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay clinical development of our product candidates.

Furthermore, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer other breakdowns, cyber-attacks or information security breaches that could compromise the confidentiality, integrity, and availability of such systems and data, expose us to liability, and affect our reputation.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. We also rely on third party vendors and their information technology systems. Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants may be vulnerable to damage from computer viruses or unauthorized access, or breached due to operator error, malfeasance or other system disruptions. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber-threats may be generic, or they may be custom-crafted against our information systems. Over the past few years, cyber-attacks have become more prevalent, intense, sophisticated and much harder to detect and defend against. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering and/or other means. We and our third party vendors may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources. Although to our knowledge we and our vendors have not experienced any such material system failure or security breach to date, if a breakdown, cyber-attack or other information security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations , whether due to a loss of trade secrets or other proprietary information or other similar disruption and we could incur liability and reputational damage. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Cyber-attacks, breaches, interruptions or other data security incidents could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, regulatory penalties, significant remediation costs, disrupt key business operations and divert attention of management and key information technology resources. In the United States, notice of breaches must be made to affected individuals, the U.S. Secretary of the Department of Health and Human Services, or HHS, and for extensive breaches, notice may need to be made to the media or U.S. state attorneys general. Such a notice could harm our reputation and our ability to compete. The HHS has the discretion to impose penalties without attempting to resolve violations through informal means. In addition, U.S. state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. There can be no assurance that we, our collaborators, CROs, vendors, and any other business counterparties will be successful in efforts to detect, prevent, protect against or fully recover systems or data from all break-downs, service interruptions, attacks or breaches of systems. In addition, we do not maintain standalone cyber-security insurance and have limited insurance coverage in the event of any breach or disruption of our or our collaborators', CROs', or vendors' systems, including any unauthorized access or loss of any personal data that we may collect, store or otherwise process. The costs related to significant security breaches or disruptions could be material and exceed the limits of any insurance coverage we may have. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, including data related to our personnel, we could incur liability and the further development and commercialization of our product candidates could be delayed and our business and operations could be adversely affected and/or could result in the loss or disclosure of critical or sensitive data, which could result in financial, legal, business or reputational harm to us.

Our business is subject to complex and evolving U.S. and foreign laws and regulations, information security policies and contractual obligations relating to privacy and data protection, including the use, processing, and cross-border transfer of personal information. These laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, or monetary penalties, and otherwise may harm our business.

We receive, generate and store significant and increasing volumes of sensitive information and business-critical information, including employee and personal data (including protected health information), research and development information, commercial information, and business and financial information. We heavily rely on external security and infrastructure vendors to manage our information technology systems and data centers. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data.

A wide variety of provincial, state, national, and international laws, and regulations apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data. These data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions. For example, the collection and use of personal data in the European Union are governed by the European Union General Data Protection Regulation ("GDPR"), which became fully effective on May 25, 2018. The GDPR imposes stringent data protection requirements, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries and in the context of clinical trials, we currently rely on patient informed consent as the legal basis for such transfers. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. The GDPR provides for penalties for noncompliance of up to the greater of €20 million or four percent of worldwide annual revenues. The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with any European Union clinical trials. GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and growth prospects.

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. For example, California recently enacted legislation, the California Consumer Privacy Act ("CCPA"), that will, among other things, require covered companies to provide new disclosures to California consumers, and afford such consumers new abilities to opt-out of certain sales of personal information, that became effective on January 1, 2020. The CCPA was amended several times throughout 2018 and 2019, and it is unclear whether further modifications will be made to this legislation or how it will be interpreted. In addition, the CCPA requires covered companies to provide new disclosures to individuals and consumers in California, and afford such individuals and consumers new data protection rights, including the ability to opt-out of certain sales of personal information. The GDPR, CCPA and many other laws and regulations relating to privacy and data protection are still being tested in courts, and they are subject to new and differing interpretations by courts and regulatory officials. Additionally, the interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. We are working to comply with the GDPR, CCPA and other privacy and data protection laws and regulations that apply to us, and we anticipate needing to devote significant additional resources to complying with these laws and regulations.

It is possible that the GDPR, CCPA or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our current policies and practices and compliance with such laws and regulations could require us to change our business practices and compliance procedures in a manner adverse to our business. We cannot guarantee that we are in compliance with all such applicable data protection laws and regulations and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations. Furthermore, other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules, and regulations, which could increase our compliance costs and the risks associated with noncompliance. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. We cannot guarantee that we or our vendors may be in compliance with all applicable international laws and regulations as they are enforced now or as they evolve. For example, our privacy policies may be insufficient to protect any personal information we collect or may not comply with applicable laws. Our non-compliance could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies,

procedures and systems. In addition, if we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts.

Our actual or perceived failure to adequately comply with applicable laws and regulations relating to privacy and data protection, or to protect personal data and other data we process or maintain, could result in regulatory enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, other lawsuits or reputational and damage, all of which could materially affect our business, financial condition, results of operations and growth prospects.

Risks Related to Development and Commercialization of Our Product Candidates

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. If clinical trials of our product candidates, particularly OC-01, 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. 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 initial 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. 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.

Each of our product candidates will require additional clinical development, management of clinical, preclinical 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 OC-01 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 and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may fail to obtain sufficient enrollment in our clinical trials or participants may fail to complete our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may decide, or regulators or institutional review boards 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 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 to suspend or terminate trials; and

- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution.

We do not know whether any of our preclinical studies or clinical trials will begin as planned, 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, 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.

We are in the process of validating our manufacturing process and to date, do not have the stability and microbiology data on our product registration batches necessary for regulatory approval for OC-01.

We are still currently collecting stability and microbiology data on our product registration batches to support NDA approval and to date we do not yet have data to support an NDA filing. We expect to report top-line results for ONSET-2 by the end of the second quarter 2020 and if results are considered approvable, we plan to submit an NDA to the FDA in the second half of 2020. However, we manufactured our FDA registration batches of 0.6 mg/ml and 1.2 mg/ml OC-01 nasal spray July and August 2019, and as the FDA requires 12 months stability data to support NDA filing, the data will not be available until after August 2020. Stability data is collected after subjecting our batches to various conditions, such as refrigeration, room temperature, and high temperatures, and it is possible that impurities, particulates, leachables, microbiology, and/or degradation of the active pharmaceutical ingredient, varenicline, or OC-01 nasal spray could occur or other issues could be detected. If the stability data is not acceptable, we may need to change our manufacturing process, which could result in a delay of the NDA submission or impact the approval of the product or both, which could materially affect our business, financial condition, results of operations and growth prospects. The FDA may also impose specific conditions, such as requiring the final product to be shipped and stored under refrigerated conditions. Any additional requirements could result in an increase in the overall cost of the product and complicate the supply chain, which could also materially affect our business, financial condition, results of operations and growth prospects.

OC-01 and our other product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale.

To date, our third-party manufacturer has only manufactured our OC-01 nasal spray in limited quantities in batch sizes appropriate for our clinical trials and registration batches to support the NDA submission, for which batch sizes are a fraction of the size we expect will be necessary for commercialization. The manufacturing processes for commercial scale are still being developed and have not been tested and the process validation requirement has not yet been satisfied. Although we plan to manufacture commercial scale batches of OC-01 nasal spray on the same manufacturing line as the registration batches, with the same equipment, only at higher scale, there are risks associated with scaling up manufacturing to commercial volumes including, among others, cost overruns, technical or other problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our manufacturer will be successful in establishing a larger-scale commercial manufacturing process for OC-01 that achieves our objectives for manufacturing capacity and cost of goods, in a timely manner or at all. In addition, there is no assurance that our manufacturers will be able to manufacture OC-01 to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of OC-01 or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of approved products for commercialization, either on a timely basis or at all, and in a cost-effective manner, our commercialization efforts would be impaired, including impacting the launch of OC-01 or inventory levels, which could materially affect our business, financial condition, results of operations and growth prospects.

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 do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements

with third parties to perform these services for each of the territories in which we may have approval to sell and market our product candidates. We may not be successful in accomplishing these required tasks.

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

Furthermore, we believe that approximately 26% of prescribing ECPs account for 80% of the volume of DED prescription treatments. If we are unable to obtain access to these ECPs or persuade adequate numbers of ECPs to prescribe our products, if and when approved, our efforts to commercialize such products will be severely inhibited, which would have a material adverse effect on our business.

Even if OC-01 or any other product candidate receives marketing approval, they may fail to achieve market acceptance by ECPs 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 OC-01 or any other product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by ECPs, patients, third-party payors and others in the medical community. Current treatments that are commonly used in the United States for DED include over-the-counter eye drops, often referred to as “artificial tears”, Restasis, Xiidra and off-label use of corticosteroids. In particular, existing prescription therapies, notably Restasis and Xiidra, are marketed by much larger biopharmaceutical companies with established brand recognition. As a result, even if OC-01 demonstrates promising or superior clinical results, including the treatment of both signs and symptoms of DED, it is possible that ECPs may continue to rely on these treatments rather than OC-01 or any other product candidate, if and when approved for marketing by the FDA. In addition, if generic versions of any products that compete with any of our product candidates are approved for marketing by the FDA, 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 OC-01 or any other product candidate 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 OC-01 or any other product candidate that we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of our product candidates compared to alternative treatments, including the existing standard of care;
- 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 of our marketing and distribution support;
- publicity concerning our products or competing products and treatments;

- the timing of market introduction of competitive products;
- 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, particularly by Medicare in light of the prevalence of DED in persons over age 55;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

Our assessment of the potential market opportunity for OC-01 and other product candidates is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, some of which we commissioned. 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 commissioned 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 opportunity for the treatment of DED in particular is difficult to precisely estimate. 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 other surveys, which may be based on a small sample size and fail to accurately reflect market opportunities. Further, we have commissioned a number of market studies that are specific to us and to our product candidates and used the results of these studies to help assess our market opportunity. While we believe that our internal assumptions and the bases of our commissioned studies 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 OC-01 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.

Even if we obtain regulatory approval for any of our product candidates, we may be subject to ongoing regulatory obligations or post-marketing commitments as specified by the FDA or other regulatory authorities, which may result in additional costs associated with those commitments.

If we obtain regulatory approval for OC-01 or any other product candidate, such approved products will be subject to continual regulatory review by the FDA and/or non-U.S. regulatory authorities. Additionally, any product candidates, if approved, will be subject to extensive and ongoing regulatory requirements, including labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with such products.

If FDA or a comparable foreign regulatory authority approves any of our product candidates, including OC-01, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practices (cGMP), as well as Good Clinical Practice (GCP) for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to successfully commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indications or conditions of use for which the product may be marketed or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or problems with our third-party manufacturers' processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products; and

- injunctions or the imposition of civil or criminal penalties.

Our ongoing regulatory requirements may also change from time to time, potentially harming or making costlier our commercialization efforts. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or other countries. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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 OC-01 for the treatment of DED, and will face competition with respect to OC-01 for other indications and any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. 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.

The DED market is already served by a variety of competing products. Many of these existing products have achieved widespread acceptance among ECPs, patients and payors. In addition, certain of these products are available, or may become available, on a generic basis, and our product candidates may not demonstrate sufficient additional clinical benefits to ECPs, patients or payors to justify a higher price compared to generic products. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of generic products.

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 or other regulatory 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, seeking to encourage the use of generic products. Generic products are currently being used for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If our product candidates are approved for marketing, such claims could still result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of such products, our manufacturing processes and facilities or our marketing programs. These investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or

eventual outcome, liability claims may also result in injury to our reputation, withdrawal of clinical trial participants, costs to defend the related litigation, a diversion of management's time and our resources, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business and cause our stock price to decline. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain or obtain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including those caused by product liability claims.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

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

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act (FCPA) or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

Following the United Kingdom's departure from the EU on January 31, 2020, commonly referred to as "Brexit", there is a "transition period" ending December 31, 2020 during which the United Kingdom will essentially be treated as a Member State of the EU and the regulatory regime will remain the same across the United Kingdom and the EU. The Withdrawal Agreement allows for this "transition period" to be extended by one or two years, but the U.K. government is currently legislating to require the transition period to end on December 31, 2020 without the possibility to extend further. In that scenario, the trading relationship between the United Kingdom and the EU will be governed by whatever agreement the two parties can reach in the course of 2020. On that short timetable the United Kingdom and EU are likely to focus on ensuring tariff-free trade but it is unclear whether there would be any formal regulatory alignment between United Kingdom and EU rules after January 1, 2021. In the unlikely event that the United Kingdom leaves the EU without an agreement, so called "hard Brexit," the United Kingdom will be completely separated from a regulatory perspective from the EU immediately upon the exit date.

Since the regulatory framework for pharmaceutical products in the United Kingdom relating to quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit will materially impact the future regulatory regime which applies to products

and the approval of product candidates in the United Kingdom. In the first instance, a separate United Kingdom authorization from any centralized authorization for the EU would need to be applied for in advance of a hard Brexit or before the end of any agreed transition period. In the immediately foreseeable future, the process is likely to remain very similar to that applicable in the EU, albeit that the processes for applications will be separate. Longer term, the United Kingdom is likely to develop its own legislation that diverges from that in the EU.

Risks Related to Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

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 part on our ability to obtain and maintain patent protection in the United States and other countries with respect to OC-01, OC-02, and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patents and patent applications that we own may fail to result in issued patents with claims that protect OC-01, OC-02 or any future product candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover OC-01, OC-02 or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, if we choose to license certain patent rights in the future from third parties, we may not have the right to control the preparation, filing and prosecution of such patent applications, or to

maintain the patents, directed to technology that we license from those third parties. We may also require the cooperation of our future licensor, if any, in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, any licensed patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by any of our future licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

If the patent applications we hold or may in-license in the future with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for OC-01, OC-02 or any future product candidate, it could dissuade other companies from collaborating with us to develop product candidates, and threaten our ability to commercialize OC-01, OC-02 or future product candidates. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our own patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. 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 products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and patents in which we have an interest may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity 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. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay incurred by the USPTO in examining the patent application (patent term adjustment). The scope of patent protection may also be limited.

Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. 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. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and specifics of FDA marketing approval of OC-02 and future product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during drug development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is based on the first approved use of a product and is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other

countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

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 noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or any of our licensors fail to maintain the patents and patent applications covering OC-01, OC-02 or any future product candidate, our competitors may be able to enter the market, which would have an adverse effect on our business.

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 current and future product candidates in any jurisdiction.

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, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent the development and commercialization of OC-01, OC-02, and any future product candidate.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation, and administrative law proceedings, inter partes review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and future product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future product candidates may infringe.

We are aware of three issued U.S. patents owned by Pfizer (U.S. Pat. No.: 7,265,119 (the ‘119), 6,890,927 (the ‘927) and 6,410,550 (the ‘550)) that Pfizer has listed in the Orange Book as covering its varenicline tartrate product, which is marketed as Chantix as an aid to smoking cessation treatment. Certain claims of these three patents are directed toward the compound varenicline tartrate and related salts thereof, and therefore may be relevant to our candidate OC-01. Of the three issued patents, we anticipate that only the ‘119 and the ‘927 will be in force at the time that we could expect to receive FDA approval of OC-01 and on October 18, 2019, we entered into a non-exclusive patent license for these patents. The ‘550 is listed in the Orange Book as expiring May 10, 2020, with pediatric exclusivity expiring November 10, 2020, and based on our current development plans, we anticipate that both the patent and pediatric exclusivity associated with the ‘550 will no longer be in force at the time of our expected FDA approval. However, even with the aforementioned license, we cannot provide assurances that third parties won’t allege infringement, which could delay or prevent the development and commercialization of OC-01 or other product candidates.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon their rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process, methods of treating certain diseases or conditions that we are pursuing with our product candidates, our formulations including combination therapies, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our current and future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use or misappropriations, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more patent of ours or any of our current or future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. 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, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex

parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For any patents and patent applications that we license from third parties, we may have limited or no right to participate in the defense of such licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also 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 an adverse effect on the price of our common shares.

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 in-licensed patents, any patents that may be issued as a result of our 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 U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and implemented wide-ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, and defending patents covering OC-01, OC-02 and any future product candidate throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may have or obtain patent protection, but where patent enforcement is not as strong as that in the United States. These unauthorized products may compete with our products in such jurisdictions and take away our market share where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Our future reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on third parties to manufacture OC-01, OC-02 and any future product candidates, and we expect to collaborate with third parties on the continuing development of OC-01, OC-02 and any future product candidates, we must, at times, share trade secrets with them. We also expect to conduct R&D programs that may require us to share trade secrets under the terms of our partnerships or agreements with CROs. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality and use restrictions and obligations, including material transfer agreements, consulting agreements, manufacturing and supply agreements, confidentiality agreements or other similar agreements with our advisors,

employees, contractors, CMOs, CROs, other service providers and consultants prior to disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors CMOs, CROs, other service providers and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

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

We employ individuals who were previously employed at other biotechnology or pharmaceutical 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 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 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. The following examples are illustrative:

- others may be able to make formulations or compositions that are the same as or similar to our current and future product candidates, but that are not covered by the claims of the patents that we own;
- others may be able to make product that is similar to our current and future product candidates we intend to commercialize that is not covered by the patents that we exclusively licensed and have the right to enforce;
- we, any of our future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- we or any of our future licensor 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 future patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as 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; and

- we may not develop additional proprietary technologies that are patentable.

Any collaboration or partnership arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current and future product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

If our future trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks,

trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, growth prospects, operating results and financial condition.

If we fail to comply with our obligations under any license, collaboration or other agreements, including our license agreement with Pfizer, such agreements may be terminated, we may be required to pay damages and we could lose intellectual property rights that are necessary for developing and protecting our product candidates.

We currently and may in the future license from third parties certain intellectual property relating to current and future product candidates. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Specifically, our license agreement with Pfizer can be terminated by Pfizer upon 60 days' written notice for our uncured material breach or 30 days following non-payment or immediately upon our insolvency.

Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any of our licensors and us and our partners.

If disputes over intellectual property that we license prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our current or future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities.

Further, we or our current or future licensors, if any, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our current or future licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, even where we have the right to control patent prosecution of patents and patent applications under a license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our acquired technologies and current or future licensed technology may be subject to retained rights. Our predecessors or licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether

our predecessors or future licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired technologies or current or future licensed technologies, or if we lose our rights to critical acquired or in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies, and current or future licensed technology, into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidates.

Risks Related to Government Regulation

If the FDA does not conclude that OC-01 satisfies the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act (FFDCA), or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates may take longer, cost more or entail greater complications and risks than anticipated, and may not be successful.

We intend to seek FDA approval through the Section 505(b)(2) regulatory pathway for OC-01. Section 505(b)(2) of the FFDCA permits the submission of a New Drug Application (NDA) where some or all of the data required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Our ability to rely on certain of the FDA's findings of safety and effectiveness in approval of another NDA or on studies published in the scientific literature will depend on our ability to demonstrate the relevance to OC-01.

In particular, we conducted ZEN, a comparative pharmacokinetic "bridge" trial, to evaluate the relative bioavailability of varenicline administered as a nasal spray (OC-01) compared to varenicline administered orally (Chantix) in order to reference certain FDA conclusions regarding the safety of varenicline from the Agency's review of the Chantix NDA. If the FDA does not accept or disagrees with our conclusions from ZEN or the data required for approval of our Section 505(b)(2) NDA are different than anticipated, we may be required to conduct additional development activities or studies or provide additional data and information to pursue the 505(b)(2) regulatory pathway on our proposed timeline. Such delays could result in new competitive products reaching the market faster than OC-01, which could materially adversely impact our competitive position and growth prospects.

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, a U.S. federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018 and 2019, may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. In addition, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical trials that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any of our NDAs.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;

- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;

- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;

- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;

- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which could materially affect our business, financial condition, results of operations and growth prospects.

We may face difficulties from changes to current regulations and future legislation.

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. Some of the provisions of the ACA have yet to be implemented, and there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have passed. On December 22, 2017, President Trump signed into law federal tax legislation commonly referred to as the Tax Cuts and Jobs Act (Tax Act) which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA 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 January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In July 2018, the Centers for Medicare and Medicaid Services (CMS) published a final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment

program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2027 unless additional Congressional action is taken. 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. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. There has been heightened governmental scrutiny recently 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 released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of prescription drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. Additionally, on January 31, 2019, HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufactures to Medicare Part D plan sponsors, Medicaid managed care organizations, and those entities' pharmacy benefit managers, the purpose of which is to further reduce the cost of drug products to consumers. 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.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever- increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, comply with data privacy and security laws and accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care 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. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a code of business conduct and ethics with respect to our employees, agents and contractors, it is not always possible to identify and deter misconduct by these 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 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 penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring 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 our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or waste Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not currently maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or EMA grants

marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

In addition, we may choose to conduct international clinical trials. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the U.S. population and U.S. medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (3) audits by regulatory authorities of the clinical data do not identify significant data integrity issues. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Our business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

We recently completed a trial and may plan to initiate additional trials in countries other than the United States. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the healthcare providers, including ECPs, who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, growth prospects, operating results and financial condition.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may

be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely adversely affect our business.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, if we receive marketing approval for OC-01 as a treatment for the signs and symptoms of DED, physicians may nevertheless use our product for their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, growth prospects, operating results and financial condition.

Inadequate funding for the FDA, the SEC 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 FDA have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission (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 drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2013, 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. 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.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs, suppliers, and other contractors and consultants, could be subject to wildfires, earthquakes, tsunamis, power shortages or outages, floods or monsoons, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war (including trade wars), political instability or other conflict, and other natural or man-made disasters or other events outside of our control that can disrupt business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. For example, we rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain supplies of our product candidates or other necessary supplies could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. All of our operations including our corporate headquarters are located in a single location in Princeton, New Jersey. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

Risks Related to Reliance on Third Parties

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

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 OC-01 and OC-02, and we expect to continue to rely upon third parties to conduct additional clinical trials of OC-01, OC-02 and potential future product candidates. Third parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third party, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, it would delay our development activities.

Our reliance on these third parties for such development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA 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, EMA 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 regulations. In addition, our clinical trials must be conducted with product produced under current 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. 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.

We contract with third parties for the production of our product candidates for preclinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements. If we were to experience an unexpected loss of supply of OC-01, OC-02 or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;

- the failure of third-party contractors to comply with applicable regulatory requirements, including manufacturing drug supply pursuant to strictly enforced cGMPs;

- the failure of the third party to manufacture our product candidates according to our specifications;

- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;

- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and

- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations.

We currently rely on single source manufacturers and suppliers for the supply of OC-01 and OC-02. If we decide to move to different or add additional manufacturers and suppliers in the future, any such transition or addition would require significant efforts in testing and validating the manufacturing and formulation process and could result in delays or other issues, which could have an adverse effect on the supply of our product candidates.

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

We may pursue collaborations with third parties for the development or commercialization of our product candidates. If we decide to pursue collaborations, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans. If we do enter into collaborations that are not successful, we may not be able to capitalize on the market potential of these product candidates.

Our development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. 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.

We would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we 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 design or results of clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future 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 them as having the requisite potential to demonstrate safety and efficacy.

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. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, 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 a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales and marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development 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.

Our business operations and current and future relationships with healthcare professionals, clinical investigators, consultants, patient organizations, customers, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, including ECPs, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- 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;

- the federal Physician Payments Sunshine Act 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 payments and other transfers of value to

physicians and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported is publicly available on a searchable website, with disclosure required annually; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology 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. Some state laws require biotechnology companies to report information on the pricing of certain drug products. State and foreign laws also 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. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation (GDPR), which 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 ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable EU laws and regulations are not successful, it could adversely affect our business in the European Union.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices, including the provision of stock options as compensation for consulting services to physicians and other healthcare providers, some of whom may be in a position to recommend, purchase and/or prescribe our product candidates, if approved, 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 governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Ownership of Common Stock

We will need substantial additional funding in the future. If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed significant amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue to conduct clinical trials of, and seek marketing approval for, OC-01, OC-02 and any other future product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for any of our product candidates, including OC-01, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. In addition, we have incurred and will continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of December 31, 2019, we had $139.1 million in cash and cash equivalents. Although we believe that our available cash and cash equivalents will be sufficient to fund our planned operations for at least 12 months following the date of this Annual Report on Form 10-K, this belief is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Advancing the development of OC-01, OC-02 and any other future product candidates will require a significant amount of capital. Our existing cash and cash equivalents may not be sufficient to fund all of the activities that are necessary to complete the development of OC-01, OC-02 and any other future product candidates. We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing, which may dilute our stockholders or restrict our operating activities. The amount of additional capital we will need to raise will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of operational, financial and management systems; and
- the costs associated with being a public company.

We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our business, growth prospects, operating results and financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

An active trading market for our common stock may not be sustained.

Prior to the closing of our IPO in November 2019, there was no public trading market for our common stock. Although our common stock is listed on the NASDAQ Global Select Market, the market for our shares has demonstrated varying levels of trading activity. We cannot predict the prices at which our common stock will trade or whether an active trading market will be sustained in the future. The lack of an active market may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the market value of their shares and may impair our ability to raise capital.

If securities or industry analysts do not continue to publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If no additional securities or industry analysts commence coverage of us, our stock price could be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the timing and results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- changes or expected changes to government and such implications for the health care industry;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of February 21, 2020, we had 21,366,950 shares of common stock outstanding. Of these shares, approximately 3,278,800 shares sold in our IPO may be resold in the public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, 17,865,320 shares of our common stock are currently restricted as a result of securities laws or lock-up agreements, but will be able to be sold in the public market as early as April 28, 2020, which is 180 days following the date of our final prospectus filed with the SEC on October 31, 2019 pursuant to Rule 424(b) under the Securities Act of 1933, as amended, as further described below. Moreover, holders of an aggregate of 14,193,281 shares of our common stock have 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. In addition, on October 31, 2019, we filed a registration statement on Form S-8 registering 5,822,484 shares of common stock that we may issue under our equity incentive plans. As a result, shares registered under this registration statement on Form S-8 can be freely sold in the public market subject to the satisfaction of vesting arrangements and the exercise of such options, volume limitations applicable to affiliates and the lock-up agreements described below.

We and our executive officers, directors and the holders of substantially all of our common stock have entered into market stand-off agreements with us and lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell, directly or indirectly, any shares of common stock without the permission of J.P. Morgan Securities LLC, Cowen and Company, LLC, and Piper Jaffray & Co. through April 27, 2020. We refer to such period as the lock-up period. When the lock-up period expires, we and our securityholders subject to a lock-up agreement or market stand-off agreement could sell our shares in the public market, which could cause our stock price to fall. In addition, J.P. Morgan Securities LLC, Cowen and Company, LLC, and Piper Jaffray & Co. may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason prior to April 28, 2020. Sales of a substantial number of such shares upon expiration of the lock-up and market stand-off agreements, the perception that such sales may occur, or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 72% of our voting stock. As a result, this group of stockholders will have the ability to control all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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 Jumpstart Our Business Startups Act of 2012 (JOBS Act). For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide 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 in our periodic reports;
- not being required to comply with the auditor attestation requirements of Section 404 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;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we may 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 will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We have identified material weaknesses in our internal control over financial reporting and, if our remediation of the material weaknesses is not effected in a timely manner or it is not effective or if we identify additional material weaknesses in the future, we may not be able to accurately or timely report our financial results, or prevent fraud, and investor confidence in our company and the market price of our shares may be adversely affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act), requires that we evaluate and determine the effectiveness of our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

During 2019, in connection with the audits of our financial statements as of and for the years ended December 31, 2018 and 2017, we identified two material weaknesses in our control over financial reporting.

First, we did not design or maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lack a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. This material weakness contributed to an additional material weakness in that we did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries.

These material weaknesses resulted in an audit adjustment to decrease operating expenses and accounts payable in the year ended December 31, 2018, and audit adjustments to the income tax footnote in the year ended December 31, 2019, that were not

material. Additionally, each of the above material weaknesses could result in a misstatement of the aforementioned account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

We have started to take some of the following steps to address the internal control deficiencies that contributed to the material weakness:

- hiring of additional finance and accounting personnel with prior experience working for finance departments of public companies and technical accounting experience, supplemented by third-party resources;
- documenting and formally assessing our accounting and financial reporting policies and procedures; and
- assessing significant accounting transactions and other technical accounting and financial reporting issues, preparing accounting memoranda addressing these issues and maintaining these memoranda in our corporate records.

However, our efforts are still preliminary and our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2019, our disclosure controls and procedures were not ineffective due to the material weaknesses in our control environment and formal accounting policies.

While we believe that these efforts, including working to formalize and implement our accounting policies and internal controls and the related documentation, will improve our internal control over financial reporting, the implementation of these measures is ongoing and will require validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles. We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal controls over financial reporting. Accordingly, there could continue to be a reasonable possibility that these deficiencies or others could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. Additionally, if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an “emerging growth company.” We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have and will continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating expenses. We cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

In addition, as a public company we will be required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our second annual report on Form 10-K after we become a public company, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. 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, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

Provisions in our restated certificate of incorporation and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our restated certificate of incorporation and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a poison pill);
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and

- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL) prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be 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 bylaws 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 claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This exclusive-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, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. If a court were to find this exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. Nothing in our amended and restated bylaws, including the exclusive-forum provision, precludes stockholders that assert claims under the Securities Act or the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.

Our net operating loss carryforwards (NOLs) could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Under the Tax Act, our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning after December 31, 2017 is limited. It is uncertain if and to what extent various states will conform to the Tax Act. As of December 31, 2019, we had U.S. federal and state NOLs of $59.1 million, and $60.7 million, respectively, which will expire beginning in the year 2035.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "5-percent stockholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. We have determined that no significant limitation would be placed on the utilization of our net operating loss and tax credit carryforwards due to prior ownership change. Our ability to utilize those NOLs could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are currently located in Princeton, New Jersey, where we lease 12,007 square feet of office space pursuant to an amended lease agreement that expires on June 30, 2022. In January 2020, we amended our corporate headquarter lease to increase the office space from 8,607 square feet to 12,007 square feet. We believe that our existing facilities are adequate for our near-term needs, but expect to need additional space as we grow. We believe that suitable additional or alternative space would be available as required in the future on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business, financial condition, results of operations or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock has been listed on the NASDAQ Global Select Market under the symbol "OYST" since October 31, 2019. Prior to this date, there was no public market for our common stock.

Holders of Common Stock

As of February 21, 2020, there were approximately 80 holders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Dividend Policy

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

Recent Sales of Unregistered Securities

During the year ended December 31, 2019, we granted stock options to purchase an aggregate of 1,417,351 shares of common stock to our directors, officers, employees, consultants and other service providers under our 2016 Equity Incentive Plan (the 2016 Plan) at exercise prices per share ranging from $5.33 to $14.28. During the same period, we issued and sold to our directors, officers, employees, consultants and other service providers an aggregate of 7,291 shares of common stock upon the exercise of options under our 2016 Plan at an exercise price per share of $1.02, for an aggregate exercise price of $7,437.

Also during the year ended December 31, 2019, we issued and sold an aggregate of 6,581,590 shares of our Series B preferred stock at a purchase price of $14.13 per share for aggregate proceeds of $93.0 million.

We believe that the offers, sales and issuances of the securities described above were exempt from registration under the Securities Act under either (1) Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering or (2) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. 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.

Use of Proceeds from Initial Public Offering

On October 30, 2019, the U.S. Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-234104), as amended, filed in connection with our initial public offering ("IPO"). The IPO closed on November 4, 2019. In connection with the IPO, we issued and sold an aggregate of 5,750,000 shares of our common stock, including 750,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a price to the public of $16.00 per share. The aggregate offering price for shares sold in the offering was $92.0 million. J.P. Morgan Securities LLC, Cowen and Company, LLC and Piper Jaffray & Co. acted as the joint book-running managers of the offering. After deducting underwriting discounts, commissions and offering expenses paid or payable by us, the net proceeds from the IPO were $82.1 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in our planned use of the net proceeds from our IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 31, 2019.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

ITEM 6. SELECTED FINANCIAL DATA

You should read the selected historical financial data below 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 Annual Report on Form 10-K. The selected financial data set forth below is derived from our audited financial statements and may not be indicative of future operating results.

	Year Ended December 31,	
	2019	2018
	(in thousands, except per share data)	
Statements of Operations and Comprehensive Loss Data:		
Operating expenses		
Research and development	$ 33,628	$ 13,755
General and administrative	13,673	2,981
Total operating expenses	47,301	16,736
Loss from operations	(47,301)	(16,736)
Interest income	1,590	233
Related party interest expense	—	—
Net loss and comprehensive loss	$ (45,711)	$ (16,503)
Net loss attributable to common stockholders	$ (45,711)	$ (16,503)
Net loss per share attributable to common stockholders, basic and diluted	$ (9.97)	$ (11.69)

	As of December 31,	
	2019	2018
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 139,147	$ 5,228
Working capital [(1)]	136,781	4,678
Total assets	143,209	5,704
Total liabilities	5,911	946
Redeemable convertible preferred stock	—	43,001
Accumulated deficit	(84,231)	(38,520)
Total stockholders' equity (deficit)	137,298	(38,243)

(1) We define working capital as current assets less current liabilities.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described, in or implied, by these forward-looking statements. Please also see the section of this Annual Report on Form 10-K titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases. Our lead product candidate OC-01 (varenicline), a highly selective nicotinic acetylcholine receptor (nAChR) agonist, is being developed as a nasal spray to treat the signs and symptoms of dry eye disease (DED). OC-01's novel mechanism of action is designed to re-establish tear film homeostasis by activating the trigeminal parasympathetic pathway and stimulating the glands and cells responsible for natural tear film production. In our Phase 2b clinical trial (ONSET-1) in 182 subjects, OC-01 demonstrated statistically significant improvements (as compared to placebo) in both signs and symptoms of DED. Based on OC-01's clinical trial results and its rapid onset of action, we believe OC-01, if approved, has the potential to become the new standard of care and redefine how DED is treated for millions of patients. We initiated a

Phase 3 clinical trial (ONSET-2) in July 2019 and expect to report top-line results by the end of the second quarter 2020. Based on the results from this second registrational trial, we plan to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2020. We believe that targeting the parasympathetic nervous system through the use of locally administered cholinergic agonists has the potential to treat a wide range of diseases and disorders. We have identified several indications, including several outside of ophthalmology, where we believe this approach could provide a meaningful benefit to patients.

Since our formation in June 2015, we have devoted substantially all of our resources to developing our product candidates. We have incurred significant operating losses to date. Our net losses were $45.7 million and $16.5 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $84.2 million. We expect that our operating expenses will increase significantly as we advance our product candidates through preclinical and clinical development, seek regulatory approval, and prepare for and, if approved, proceed to commercialization; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. In addition, we have incurred and will continue to incur additional costs associated with operating as a public company.

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

We plan to continue to use third-party service providers, including clinical research organizations (CROs) and contract manufacturing organization (CMOs), to carry out our preclinical and clinical development and to manufacture and supply the materials to be used during the development and commercialization of our product candidates. We do not currently have a sales force. If OC-01 is approved for the treatment of the signs and symptoms of DED, we intend to deploy a specialty sales force at launch of approximately 150 to 200 field representatives.

Prior to our initial public offering (IPO), we funded our operations primarily from the sale and issuance of redeemable convertible preferred stock and convertible promissory notes. In February and April 2019, we raised net proceeds of $92.9 million from the sale of Series B redeemable convertible preferred stock.

In October 2019, we entered into a non-exclusive patent license agreement with Pfizer, pursuant to which we made an upfront payment of $5.0 million. If we successfully commercialize OC-01, we may be required to pay a single milestone payment in the very low double-digit millions and tiered royalties on net sales of OC-01 at percentages ranging from the mid-single digits to the mid-teens.

On November 4, 2019, we completed our IPO selling 5,750,000 shares of our common stock at $16.00 per share. Proceeds from our IPO, net of underwriting discounts and commissions and other offering expenses, were $82.1 million. In connection with the completion of our IPO on November 4, 2019, all then outstanding shares of redeemable convertible preferred stock converted into 14,193,281 shares of common stock.

As of December 31, 2019, we had cash and cash equivalents of $139.1 million. We believe that those cash and cash equivalents will be sufficient to fund our projected operations for at least 12 months from the issuance date of our financial statements as of and for the year ended December 31, 2019.

Components of Operating Results

Revenue

We have not generated any revenue from product sales and do not expect to do so in the near future.

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our product candidates. These expenses include fees paid to third parties to conduct certain research and development activities on our behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for employees dedicated to our research and product development and allocated overhead expenses, including rent, equipment, depreciation, information technology costs and utilities. We expense both internal and external research and development expenses as they are incurred.

We do not allocate our costs by product candidate, as a significant amount of research and development expenses include internal costs, such as payroll and other personnel expenses, laboratory supplies and allocated overhead expenses, and external costs, such as fees paid to third parties to conduct research and development activities on our behalf, are not tracked by product candidate. In particular, with respect to internal costs, several of our departments support multiple product candidate research and development programs, and therefore the costs cannot be allocated to a particular product candidate or development program. The following table shows our research and development expenses by type of activity (in thousands):

	Year Ended December 31,	
	2019	**2018**
Clinical and preclinical	$ 12,470	$ 9,302
Chemistry, Manufacturing and Controls (CMC)	12,148	2,885
License costs	5,000	—
Regulatory and other costs	4,010	1,568
Total research and development expenses	$ 33,628	$ 13,755

We are focusing substantially all of our resources on the development of our product candidates, particularly OC-01. We expect our research and development expenses to increase substantially for at least the next few years, as we seek to initiate additional clinical trials for our product candidates, complete our clinical programs, pursue regulatory approval of our product candidates and prepare for the possible commercialization of these product candidates. Predicting the timing or cost to complete our clinical programs or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, allocated overhead expenses, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the applicable stock exchange and Securities and Exchange Commission (SEC) requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Interest Income

Interest income consists primarily of interest income earned on our cash and cash equivalents.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the periods indicated (in thousands, except percentages):

	Year Ended December 31,			
	2019	2018	Change	%
Operating expenses:				
Research and development	$ 33,628	$ 13,755	$ 19,873	144 %
General and administrative	13,673	2,981	10,692	359 %
Loss from operations	(47,301)	(16,736)	(30,565)	183 %
Interest income	1,590	233	1,357	582 %
Net loss	$ (45,711)	$ (16,503)	$ (29,208)	177 %

Research and Development Expenses

Research and development expenses increased by $19.9 million, or 144%, from the year ended December 31, 2018 to the year ended December 31, 2019. The increase in research and development expenses was primarily due to our advancement of OC-01 and reflected an increase in fees due to CROs and CMOs of $12.5 million, an increase of $5.0 million related to the license acquisition payment made to Pfizer and an increase in payroll and personnel-related expenses, including salaries and bonuses, benefits and stock-based compensation expense, of $2.4 million. We expect that our research and development expenses will continue to increase as we continue to add personnel to support our research and development activities and incur further expenses for CROs and CMOs in order to continue the advancement of our product candidates.

General and Administrative Expenses

General and administrative expenses increased by $10.7 million, or 359%, from the year ended December 31, 2018 to the year ended December 31, 2019. The increase in general and administrative expenses was primarily due to the expansion of our organization and reflected an increase in payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense, of $4.4 million, an increase in professional services and other expenses incurred in relation to our IPO readiness of $3.5 million, an increase in marketing expenses, of $1.5 million, an increase in facilities expenses, consisting primarily of rent and depreciation, of $0.3 million; and an increase in other general and administrative expenses of $1.0 million.

Interest Income

Interest income increased by $1.4 million, or 582%, from the year ended December 31, 2018 to the year ended December 31, 2019, primarily due to an increase in cash and cash equivalents as a result of the IPO in November 2019 and the sale of Series B redeemable convertible preferred stock in February and April 2019.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation in 2015 through December 31, 2019, we have funded our operations with an aggregate of $213.4 million in gross cash proceeds from the sale of redeemable convertible preferred stock and convertible promissory notes and the gross cash proceeds from our IPO. In February and April 2019, we received net cash proceeds of $84.9 million and $8.0 million, respectively, from the sale of Series B redeemable convertible preferred stock. On November 4, 2019, we received $82.1 million of net proceeds upon completion of our IPO.

As of December 31, 2019, we had cash and cash equivalents of $139.1 million.

Future Funding Requirements

We have incurred net losses since our inception. For the years ended December 31, 2019 and 2018, we had net losses of $45.7 million and $16.5 million, respectively. As of December 31, 2019, we had an accumulated deficit of $84.2 million. We believe that our existing cash and cash equivalents in the amount of $139.1 million will be sufficient to fund our projected operations for at least 12 months from the issuance date of our financial statements as of and for the year ended December 31, 2019.

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates or enter into collaborative agreements with third parties,

and we do not know when, or if, either will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. 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 extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of operational, financial and management systems; 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 failure to raise capital as and 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 when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials or we may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

See the section of this Annual Report on 10-K titled “Risk Factors” for additional risks associated with our substantial capital requirements.

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,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	$ (40,815)	$ (17,083)
Investing activities	(200)	—
Financing activities	174,985	—
Net increase (decrease) in cash, cash equivalents and restricted cash	133,970	(17,083)

Cash Flows from Operating Activities

Net cash used in operating activities was $40.8 million for year ended December 31, 2019. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of $45.7 million, adjusted by non-cash stock-based compensation expense of $3.3 million and by a decrease in changes in assets and liabilities of $1.6 million. Decrease in changes in assets and liabilities included an increase in prepaid expenses and other current assets of $2.6 million due to change in prepayments made to CROs and CMOs, offset by an increase in accrued liabilities of $4.2 million due to an increase in accrued research and development expenses and professional fees.

Net cash used in operating activities was $17.1 million for the year ended December 31, 2018. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of $16.5 million, increased by a decrease in accrued liabilities of $1.2 million primarily due to a decrease in accrued research and development and accrued compensation expenses, and partially offset decrease in prepaid expenses and other current assets of $0.5 million.

Cash Flows used in Investing Activities

Net cash used in investing activities was $0.2 million for the year ended December 31, 2019, which related to the purchase of property and equipment. Net cash used in investing activities was zero for the year ended December 31, 2018.

Cash Flows from Financing Activities

Net cash provided by financing activities was $175.0 million for the year ended December 31, 2019, due to net proceeds from the sale of Series B redeemable convertible preferred stock of $92.9 million and net proceeds from the IPO of $82.1 million.

We did not undertake any financing activities in the year ended December 31, 2018.

Contractual Obligations and Commitments

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

	Payments Due by Period (in thousands)		
	Less than 1 year	1 to 3 years	Total
Operating lease obligations (1)	$ 319	$ 502	$ 821

(1) We lease our office facilities in Princeton, New Jersey under two non-cancellable operating leases with an expiration dates of March 15, 2020 and July 31, 2022. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.

In January 2020 we amended one lease of our office facilities in Princeton, New Jersey to include additional office space, with an expiration date of July 31, 2022. Total future minimum lease payments under this amendment are $0.4 million.

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

In October 2016, we entered into an asset purchase agreement pursuant to which we acquired the compound OC-02. Under this agreement we are obligated to make milestone payments of up to an aggregate of $37.0 million upon achievement of certain development and regulatory milestone events. In March 2018, we made a payment of $1.5 million upon completion of the first of these milestones. We accrued such amount as of December 31, 2017 as we concluded that it was probable that such payment would be made. Under the asset purchase agreement, we are also obligated to make royalty payments at a mid-single digit percentage rates on net worldwide sales of the covered products. In addition, we are required to pay 15% of any (i) licensing revenue we receive that is related to OC-02 and (ii) revenue received from the sale of OC-02, up to a maximum aggregate amount of $10.0 million. These commitments are not included in the table above due to uncertainty of timing of any such payments.

In October 2019, we entered into a non-exclusive patent license agreement (the License Agreement) with Pfizer, which granted us non-exclusive rights under Pfizer's patent rights covering varenicline tartrate to develop, manufacture, and commercialize our OC-01 varenicline product candidate. Under the terms of the License Agreement, we made an upfront payment to Pfizer of $5.0 million. If we successfully commercialize OC-01, we may be required to pay a single milestone payment in the very low double-digit millions and tiered royalties on net sales of OC-01 at percentages ranging from the mid-single digits to the mid-teens. The royalty obligation to Pfizer will commence upon first commercial sale of OC-01 and will expire upon the later of (a) the expiration of all regulatory or data exclusivity granted to Pfizer in connection with varenicline in the United States; and (b) the expiration or abandonment of the last valid claims of the licensed patents. These commitments are not included in the table above due to uncertainty of timing of any such payments.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements 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 assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. For more detail on our critical accounting policies, refer to Note 1 "Organization and Summary of Significant Accounting Policies" to our audited financial statements included elsewhere in this Annual Report on Form 10-K.

Accrued Research and Development

We have entered into various agreements with CMOs and CROs. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. To date, our estimated accruals have not differed materially from the actual costs.

Stock-Based Compensation

We use a fair value-based method to account for all stock-based compensation arrangements with employees and non-employees, including stock options and stock awards. The fair value of the option granted is recognized on a straight-line basis over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period, which usually is the vesting period. We account for forfeitures as they occur. In determining fair value of the stock options granted, we use the Black–Scholes model, which requires the input of subjective assumptions. These assumptions include: estimating the length of time employees will retain their vested stock options before exercising them (expected term), the estimated volatility of our common stock price over the expected term (expected volatility), risk-free interest rate and expected dividends. Changes in the following assumptions can materially affect the estimate of fair value and ultimately how much stock-based compensation expense is recognized; and the resulting change in fair value, if any, is recognized in our statement of

operations and comprehensive loss during the period the related services are rendered. There are several assumptions that are required in the Black Scholes model.

- *Expected Term* – The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.

- *Expected Volatility* – We use an average historical stock price volatility of a peer group of comparable publicly traded companies in biotechnology and pharmaceutical related industries to be representative of its expected future stock price volatility, as we do not have any trading history for our common stock. For purposes of identifying these peer companies, we consider the industry, stage of development, size and financial leverage of potential comparable companies. For each grant, we measure historical volatility over a period equivalent to the expected term.

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

- *Risk-Free Interest Rate* – The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equivalent to the expected term of the stock award.

Common Stock Valuations prior to our IPO

Prior to our IPO, the estimated fair value of the common stock underlying our stock options and stock awards was determined at each grant date by our board of directors, with input from management. All options to purchase shares of our common stock were intended to be exercisable at a price per share not less than the per-share fair value of our common stock underlying those options on the date of grant.

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

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

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

- external market conditions affecting the pharmaceutical and biotechnology industry and trends within the industry;

- our stage of development and business strategy;

- the rights, preferences and privileges of our redeemable convertible preferred stock relative to those of our common stock;

- the prices at which we sold shares of our redeemable convertible preferred stock;

- our financial condition and operating results, including our levels of available capital resources;

- the progress of our research and development efforts;

- equity market conditions affecting comparable public companies; and

- general U.S. market conditions and the lack of marketability of our common stock.

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

- *Option Pricing Method.* Under the option pricing method, or OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these

- *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 OPM method as well as a hybrid approach of the OPM and the PWERM methods were the most appropriate methods for allocating our enterprise value to determine the estimated fair value of our common stock. In valuing the equity prior to the IPO, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of our common stock at each grant date prior to our IPO reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

Common Stock Valuations following our IPO

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

Income Taxes

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

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

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

Net operating loss carryforwards and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percentage points as defined under Sections 382 and 383 in the Internal Revenue Code, which could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. We have determined that no significant limitation would be placed on the utilization of our net operating loss and tax credit carryforwards due to prior ownership changes. Subsequent ownership changes may affect the limitation in future years.

As of December 31, 2019, and 2018, we had unrecognized tax benefits, all of which would affect income tax expense if recognized, before consideration of our valuation allowance. We do not expect that our uncertain tax positions will materially change in the next 12 months.

Off-Balance Sheet Arrangements

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

Indemnification Agreements

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

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

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012 (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. However, we have chosen to irrevocably "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of our first fiscal year in which we have total annual revenues of more than $1.07 billion; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Recent Accounting Pronouncements

See the section titled "Organization and Summary of Significant Accounting Policies" in Note 1 to our financial statements included elsewhere in this Annual Report in the Form 10-K for additional information.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. As of December 31, 2019, we had cash equivalents of $138.1 million, consisting of interest-bearing money market funds for which the fair value would be affected by changes in the general level of U.S. interest rates. However, due to the short-term maturities and the low-risk profile of our cash equivalents, an immediate 10% relative change in interest rates would not have a material effect on the fair value of our cash equivalents or on our future interest income.

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found in Part IV, Item 15 of this Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2019, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of December 31, 2019, our disclosure controls and procedures were not effective due to the material weaknesses described below.

Notwithstanding the identified material weaknesses, management, including our Chief Executive Officer and our Chief Financial Officer, believes the financial statements included in this Annual Report on Form 10-K fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. GAAP.

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

Material Weaknesses in Internal Control over Financial Reporting

During 2019, in connection with the audits of our financial statements as of and for the years ended December 31, 2018 and 2017, we identified two material weaknesses in our control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The first material weakness we identified is that we did not design or maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. This material weakness contributed to an additional material weakness in that we did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries.

These material weaknesses resulted in an audit adjustment to decrease operating expenses and accounts payable in the year ended December 31, 2018, and audit adjustments to the income tax footnote in the year ended December 31, 2019, that were not material. Additionally, each of the above material weaknesses could result in a misstatement of the aforementioned account balances or disclosures that would result in a material misstatement to our annual or interim financial statements that would not be prevented or detected.

Remediation Plan

We have taken or are in the process of taking the following actions to begin to address the material weaknesses described above:

- we hired a full-time Chief Financial Officer and Controller in July 2019 and October 2019, respectively, and replaced part-time contractors used in these positions previously;

- we have hired and are continuing to actively seek to hire additional accounting and finance staff members to augment our current staff and to improve the effectiveness of our closing and financial reporting processes;

- we proactively assessed significant accounting transactions and other technical accounting and financial reporting issues, and used technical accounting consultants to prepare accounting memoranda addressing these issues;

- we have strengthened our financial statements review procedures and the supervisory reviews by our management that are performed during the financial close process; and

- we are continuing to formalize and implement our accounting policies and internal controls and the related documentation.

While we believe that these efforts will improve our internal control over financial reporting, the implementation of these measures is ongoing and will require validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles.

We believe we are making progress toward achieving the effectiveness of our internal controls and disclosure controls. The actions that we are taking are subject to ongoing management review, as well as audit committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate these material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weaknesses in our internal control over financial reporting, which may necessitate additional implementation and evaluation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the known material weaknesses expeditiously.

Changes in Internal Control over Financial Reporting

We are taking actions to remediate the material weaknesses relating to our internal controls over financial reporting, as described above in the remediation plan. Except as otherwise disclosed herein, there have been no changes in our internal control over financial reporting during year ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Management's Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after December 31, 2019 (the Proxy Statement), and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDERS MATTERS

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

(1) Financial Statements:

(2) Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or the amounts are immaterial or the required information is presented in the financial statements and notes thereto.

(3) Exhibits

The following is a list of the exhibits filed as part of this report.

Exhibit Number	Description	Form	File No.	Number	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-39112	3.1	November 5, 2019
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-39112	3.2	November 5, 2019
4.1*	Description of Securities of the Registrant.				
4.2	Form of Common Stock Certificate.	S-1/A	333-234104	4.2	October 15, 2019
4.3	Amended and Restated Investor Rights Agreement among the Registrant and certain of its stockholders, dated February 15, 2019.	S-1	333-234104	4.1	October 4, 2019
10.1^	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-234104	10.1	October 4, 2019
10.2^	2016 Equity Incentive Plan, as amended, and forms of agreement thereunder.	S-1	333-234104	10.2	October 4, 2019
10.3^	2019 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	333-234104	10.3	October 21, 2019
10.4^	2019 Employee Stock Purchase Plan.	S-1/A	333-234104	10.4	October 21, 2019
10.5^	Employment Offer Letter between the Registrant and Jeffrey Nau, Ph.D., M.M.S.	S-1	333-234104	10.5	October 4, 2019
10.6^	Employment Offer Letter between the Registrant and Daniel Lochner.	S-1	333-234104	10.6	October 4, 2019

10.7^	Employment Offer Letter between the Registrant and John Snisarenko.	S-1	333-234104	10.7	October 4, 2019
10.8^	Form of Change in Control and Severance Agreement.	S-1	333-234104	10.8	October 4, 2019
10.9^	Outside Director Compensation Policy.	S-1	333-234104	10.9	October 4, 2019
10.10^	Executive Incentive Compensation Plan.	S-1	333-234104	10.10	October 4, 2019
10.11#	Non-Exclusive Patent License Agreement between the Registrant and Pfizer Inc., dated as of October 18, 2019.	S-1/A	333-234104	10.11	October 21, 2019
23.1*	Consent of Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (contained in the signature page to this Annual Report on Form 10-K).				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*+	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

+ The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

^ Indicates management contract or compensatory plan

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OYSTER POINT PHARMA, INC.

Date: February 27, 2020

By: /s/ Jeffrey Nau

Jeffrey Nau, Ph.D., M.M.S.

President, Chief Executive Officer and Director

Date: February 27, 2020

By: /s/ Daniel Lochner

Daniel Lochner

Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey Nau and Daniel Lochner, jointly and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Data
/s/ Jeffrey Nau Jeffrey Nau, Ph.D., M.M.S.	Chief Executive Officer, President and Director (Principal Executive Officer)	February 27, 2020
/s/ Daniel Lochner Daniel Lochner	Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2020
/s/ Michael Ackermann Michael Ackermann, Ph.D.	Chair of the Board	February 27, 2020
/s/ Mark Murray Mark Murray	Director	February 27, 2020
/s/ Ali Behbahani Ali Behbahani, M.D.	Director	February 27, 2020
/s/ William J. Link William J. Link, Ph.D.	Director	February 27, 2020
/s/ Clare Ozawa Clare Ozawa, Ph.D.	Director	February 27, 2020
/s/ Benjamin Tsai Benjamin Tsai	Director	February 27, 2020
/s/ Aimee Weisner Aimee Weisner	Director	February 27, 2020

OYSTER POINT PHARMA, INC.
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Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Oyster Point Pharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Oyster Point Pharma, Inc. (the "Company") as of December 31, 2019 and 2018, and the related statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 27, 2020

We have served as the Company's auditor since 2017.

OYSTER POINT PHARMA, INC.
Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 139,147	$ 5,228
Prepaid expenses and other current assets	3,033	390
Total current assets	142,180	5,618
Restricted cash	51	—
Operating lease right-of-use asset	797	66
Property and equipment, net	181	—
Other non-current assets	—	20
Total assets	$ 143,209	$ 5,704
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 500	$ 462
Accrued liabilities	4,603	422
Operating lease liability	296	56
Total current liabilities	5,399	940
Non-current liabilities:		
Operating lease liability, non-current	512	6
Total liabilities	5,911	946
Commitments and contingencies (Note 5)		
Series A redeemable convertible preferred stock: $0.001 par value per share - no shares authorized, issued and outstanding at December 31,2019 and 7,611,691 shares authorized, issued and outstanding at December 31, 2018; liquidation preference $43,126 at December 31, 2018	$ —	$ 43,001
Stockholders' equity (deficit)		
Preferred stock: $0.001 par value per share - 5,000,000 shares authorized and no shares issued and outstanding as of December 31, 2019 and no shares authorized, issued and outstanding as of December 31, 2018	—	—
Common stock, $0.001 par value per share - 1,000,000,000 authorized shares at December 31, 2019, and 10,943,000 shares authorized at December 31, 2018; 21,366,950 shares issued and outstanding at December 31, 2019, and 1,411,966 shares issued and outstanding at December 31, 2018	21	1
Additional paid-in-capital	221,508	276
Accumulated deficit	(84,231)	(38,520)
Total stockholders' equity (deficit)	137,298	(38,243)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 143,209	$ 5,704

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

OYSTER POINT PHARMA, INC.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 33,628	$ 13,755
General and administrative	13,673	2,981
Total operating expenses	47,301	16,736
Loss from operations	(47,301)	(16,736)
Interest income	1,590	233
Net loss and comprehensive loss	$ (45,711)	$ (16,503)
Net loss per share attributable to common stockholders, basic and diluted	$ (9.97)	$ (11.69)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	4,585,146	1,411,966

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

OYSTER POINT PHARMA, INC.
Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2018	7,611,691	$ 43,001	1,411,966	$ 1	$ 122	$ (22,017)	$ (21,894)
Net loss	—	—	—	—	—	(16,503)	(16,503)
Stock-based compensation	—	—	—	—	154	—	154
Balance at December 31, 2018	7,611,691	$ 43,001	1,411,966	$ 1	$ 276	$ (38,520)	$ (38,243)
Net loss	—	—	—	—	—	(45,711)	(45,711)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $148	6,581,590	92,852	—	—	—	—	—
Issuance of common stock upon initial public offering, net of issuance cost of $9,898	—	—	5,750,000	6	82,096	—	82,102
Conversion of redeemable convertible preferred stock into common stock upon initial public offering	(14,193,281)	(135,853)	14,193,281	14	135,839	—	135,853
Stock issued through exercise of stock options	—	—	11,703	—	31	—	31
Stock-based compensation expense	—	—	—	—	3,266	—	3,266
Balance at December 31, 2019	—	$ —	21,366,950	$ 21	$ 221,508	$ (84,231)	$ 137,298

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

OYSTER POINT PHARMA, INC.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (45,711)	$ (16,503)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,266	154
Depreciation and amortization	19	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(2,643)	473
Other non-current assets	20	(20)
Accounts payable	38	44
Operating lease right-of-use asset	(731)	(66)
Operating lease liability	746	62
Accrued liabilities	4,181	(1,227)
Net cash used in operating activities	(40,815)	(17,083)
Cash flows from investing activities		
Purchases of property and equipment	(200)	—
Net cash used in investing activities	(200)	—
Cash flows from financing activities		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	92,852	—
Proceeds from initial public offering, net of issuance costs	82,102	—
Proceeds from the issuance of common stock upon exercise of stock options	31	—
Net cash provided by financing activities	174,985	—
Net increase (decrease) in cash and cash equivalents	133,970	(17,083)
Cash and cash equivalents at the beginning of the period	5,228	22,311
Cash, cash equivalents and restricted cash at the end of the period	$ 139,198	$ 5,228
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	139,147	5,228
Restricted cash	51	—
Cash, cash equivalents and restricted cash	139,198	5,228
Supplemental cash flow information		
Right-of-use for office space acquired through operating leases	$ 897	$ 113
Supplemental non-cash investing and financing activities		
Conversion of redeemable convertible preferred stock to common stock upon closing of the initial public offering	$ (135,853)	$ —

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

OYSTER POINT PHARMA, INC.
Notes to Financial Statements
(in thousands, except share and per share data)

1. Organization and Summary of Significant Accounting Policies

Description of the Business

Oyster Point Pharma, Inc. (the "Company") was incorporated on June 30, 2015. From inception through December 31, 2019, the Company has been primarily engaged in business planning, research, clinical development of its lead therapeutic product candidates, recruiting and raising capital. The Company is a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of pharmaceutical therapies to treat ocular surface diseases. The Company's principal office is located in Princeton, New Jersey.

Initial Public Offering

On November 4, 2019, the Company completed its initial public offering (IPO) selling 5,750,000 shares of common stock at a price to the public of $16.00 per share. The aggregate net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses, were $82.1 million. In addition, upon the closing the IPO, all outstanding shares of redeemable convertible preferred stock outstanding were converted into an aggregate of 14,193,281 shares of the Company's common stock.

Liquidity

Since inception, the Company has incurred recurring losses and negative cash flows from operations. The Company incurred net losses of $45.7 million and $16.5 million for the years ended December 31, 2019 and 2018, respectively, and had an accumulated deficit of $84.2 million as of December 31, 2019. The Company has historically financed its operations primarily through the sale and issuance of its securities. To date, none of the Company's product candidates have been approved for sale and therefore the Company has not generated any revenue from product sales. The Company expects to incur increased sales and marketing expenses with the commercialization of new and existing products, if approved for sale, as well as increased research and development expenses as it develops additional product candidates. The Company expects its operating losses to continue to increase for the foreseeable future.

While the Company has been able to raise multiple rounds of financing, there can be no assurance that in the event the Company requires additional financing, such financing will be available on terms that are favorable, or at all. Failure to generate sufficient cash flows from operations, raise additional capital or reduce certain discretionary spending would have a material adverse effect on the Company's ability to achieve its intended business objectives.

The Company had cash and cash equivalents of $139.1 million as of December 31, 2019. Management believes that the Company's current cash and cash equivalents will be sufficient to fund its planned operations for at least 12 months from the date of issuance of these financial statements.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

Reverse Stock Split

In October 2019, the Company's Board of Directors and stockholders approved an amendment to the Company's amended and restated certificate of incorporation to effect a 2.832861-for-1 reverse stock split of the Company's common stock and redeemable convertible preferred stock, which was effected on October 18, 2019. The par values of the common stock and redeemable convertible preferred stock were not adjusted as a result of the reverse stock split. Accordingly, all common stock, redeemable convertible preferred stock, stock options, and related per share amounts as of and for the year ended December 31, 2018 and for the period through October 18, 2019 have been retroactively adjusted to give effect to the reverse stock split.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenue and expenses in the financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to the valuation of stock awards, income taxes and certain research and development accruals and for periods prior to the IPO, the valuation of convertible notes, derivative instruments, and redeemable convertible preferred stock. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from these estimates, and such differences could be material to the Company's financial position and results of operations.

Segments

The Company operates and manages its business as one reportable operating segment. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's long-lived assets are located in the United States.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. Substantially all of the Company's cash is held by one financial institution that management believes is of high credit quality. Such deposits may, at times, exceed federally insured limits. The Company's cash equivalents are invested in highly rated money market funds.

Risks and Uncertainties

The Company operates in a dynamic and highly competitive industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: ability to obtain future financing; advances and trends in new technologies and industry standards; results of clinical trials; regulatory approval and market acceptance of the Company's products; development of sales channels; certain strategic relationships; litigation or claims against the Company related to intellectual property, product, regulatory, or other matters; and the Company's ability to attract and retain employees necessary to support its growth.

Product candidates developed by the Company will require approvals from the U.S. Food and Drug Administration or other international regulatory agencies prior to commercial sales. There can be no assurance that the product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval, it could have a materially adverse impact on the Company.

The Company has expended and will continue to expend substantial funds to complete the research, development and clinical testing of its product candidates. The Company also will be required to expend additional funds to establish commercial-scale manufacturing arrangements and to provide for the marketing and distribution of products that receive regulatory approval. The Company will require additional funds to commercialize its products. The Company is unable to entirely fund these efforts with its current financial resources. If adequate funds are unavailable on a timely basis from operations or additional sources of financing, the Company may have to delay, reduce the scope of or eliminate one or more of its research or development programs which would materially and adversely affect its business, financial condition and operations.

The Company relies on single source manufacturers and suppliers for the supply of its product candidates. Disruption from these manufacturers or suppliers would have a negative impact on the Company's business, financial position and results of operations. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less at the time of purchase to be cash equivalents. As of December 31, 2019 and 2018, cash and cash equivalents consisted of cash on deposit with a bank denominated in U.S. dollars and investment in money market funds.

Restricted Cash

As of December 31, 2019, the Company had $51,000 of long-term restricted cash deposited with a financial institution. The entire amount is held in a separate bank account to support a letter of credit agreement related to one of the Company's office facilities lease, which expires in 2022.

Property and Equipment

Property and equipment is recorded at cost and depreciated using the straight-line method over the estimated useful lives of the related assets as follows:

Office equipment	5 years
Furniture and fixtures	7 years
Leasehold improvements	Shorter of lease term or estimated useful life

Leases

The Company determines if an arrangement is or contains a lease and the classification of that lease at inception of a contract. The Company's operating lease asset is included in "operating lease right-of-use asset" ("ROU asset"), and the current and non-current portions of the operating lease liability are included in "operating lease liability", and "operating lease liability, non-current", respectively, on the balance sheets. As of December 31, 2019 and 2018, the Company had no finance leases.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the lease commencement date. Operating lease right-of-use assets are based on the corresponding lease liability adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. The Company does not account for renewals or early terminations unless it is reasonably certain to exercise these options at commencement. Operating lease expense is recognized on a straight-line basis over the lease term. The Company accounts for lease and non-lease components as a single lease component for operating leases. The Company does not record leases with terms of 12 months or less on the balance sheets.

As the implicit rate for the operating lease was not determinable, the Company used an incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future payments. The Company's incremental borrowing rate was estimated to approximate the interest rate on a collateralized basis with similar terms and payments, in an economic environment where the leased asset is located. The Company determined the incremental borrowing rate by considering various factors, such as its credit rating, interest rates of similar debt instruments of entities with comparable credit ratings, the lease term and the currency in which the lease was denominated.

Fair Value of Financial Instruments

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.

Redeemable Convertible Preferred Stock

The Company recorded all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. Redeemable convertible preferred stock was recorded outside of permanent equity because while it was not mandatorily redeemable, in certain events considered not solely within the Company's control, such as a merger, acquisition, or sale of all or substantially all of the Company's assets (each, a "deemed liquidation event"), the redeemable convertible preferred stock have become redeemable at the option of the holders of at least a majority of the then outstanding preferred shares. The Company did not adjust the carrying value of the redeemable convertible preferred stock to its liquidation preference because a deemed liquidation event obligating the Company to pay the liquidation preference to holders of shares of redeemable convertible preferred stock was not probable of occurring. All outstanding shares of redeemable convertible preferred stock were converted to common stock shares upon the closing of the IPO in November 2019.

Research and Development

Research and development expenses consist of compensation costs, employee benefit costs, costs for contract manufacturing organizations ("CMOs"), costs for clinical research organizations ("CROs"), costs for sponsored research, consulting costs, costs for laboratory supplies, costs for product licenses, facility-related expenses and depreciation. All research and development costs are charged to research and development expenses within the statements of operations and comprehensive loss as incurred.

Payments associated with licensing agreements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are also expensed as incurred.

The Company's accruals for research and development activities performed by third parties are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accruals accordingly. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and non-employees using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option pricing model. The Company uses the Black-Scholes pricing model to estimate the fair value of options granted that are expensed on a straight-line basis over the vesting period. The Company accounts for forfeitures as they occur. Option valuation models, including the Black-Scholes option-pricing model, require the input of several assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility, and the expected life of the award.

Comprehensive Loss

Comprehensive loss represents all changes in stockholders' equity (deficit) except those resulting from distributions to stockholders. There have been no items qualifying as other comprehensive income (loss) and, therefore, for all periods presented, the Company's comprehensive loss was the same as its reported net loss.

Income Taxes

The Company accounts for income taxes using the asset and liability method whereby deferred tax asset and liability accounts are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established where necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company accounts for uncertain tax positions by assessing all material positions taken in any assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. The Company recognizes interest and penalties related to unrecognized tax benefits within the income tax expense line. Accrued interest and penalties are included within the related income tax liability line in the balance sheets. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the redeemable convertible preferred stock and common stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock was a participating security. The Company's participating securities did not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") under its accounting standard codifications ("ASC") or other standard setting bodies and adopted by the Company as of the specified effective date, unless otherwise discussed below.

Recently adopted accounting pronouncements

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. Down round features are common in warrants, preferred shares and convertible debt instruments issued by private companies and early-stage public companies. 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 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, including adoption in any interim period. The amendments in Part I should be applied (1) retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the balance sheet as of the beginning of the first fiscal year and interim periods; (2) retrospectively to outstanding financial instruments with a down round feature for each prior reporting period presented. The Company adopted this ASU effective January 1, 2019. The adoption of this ASU did not have a material effect on the Company's financial statements and related disclosures.

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income.* The ASU permits companies to reclassify disproportionate tax effects in accumulated other comprehensive income ("AOCI") caused by the Tax Act to retained earnings. For public business entities, this ASU is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this ASU effective January 1, 2019. The adoption of this ASU did not have a material effect on the Company's financial statements and related disclosures.

Recently issued accounting pronouncements not yet adopted

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740) - Simplifying the Accounting for Income Taxes*, which simplify various aspects related to the accounting for income taxes. This ASU removes exceptions to the general principles in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. For public companies, this ASU is effective for interim and annual reporting periods beginning after December 15, 2020. The Company is currently evaluating the impact the adoption of this ASU will have on its financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements on fair value measurements. This ASU removes the requirement to disclose: the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; the policy for timing of transfers between levels; and the valuation processes for Level 3 fair value measurements. For public business entities, this ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact the adoption of this ASU will have on its financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This ASU replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. For SEC filers that are eligible to be smaller reporting companies, this ASU is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact the adoption of this ASU will have on its financial statements and related disclosures.

2. Fair Value Measurements

The Company assesses the fair value of financial instruments as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering

such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk.

As of December 31, 2019, financial assets measured and recognized at fair value were as follows (in thousands):

	Fair Value Measurements at December 31, 2019			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds	$ 138,147	$ —	$ —	$ 138,147
Total fair value of assets	$ 138,147	$ —	$ —	$ 138,147

As of December 31, 2018, financial assets measured and recognized at fair value were as follows (in thousands):

	Fair Value Measurements at December 31, 2018			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds	$ 5,228	$ —	$ —	$ 5,228
Total fair value of assets	$ 5,228	$ —	$ —	$ 5,228

Money market funds are included in cash and cash equivalents on the balance sheets and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

There were no financial liabilities measured and recognized at fair value as of December 31, 2019 and December 31, 2018.

3. Property and Equipment, net

Property and equipment consisted of the following (in thousands):

	December 31, 2019
Leasehold improvements	$ 105
Office equipment	45
Furniture and fixtures	50
	200
Accumulated depreciation	(19)
Property and equipment, net	$ 181

The Company did not have any property and equipment as of December 31, 2018.

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2019	2018
Accrued compensation	$ 1,214	$ 367
Accrued professional services	1,163	35
Accrued research and development expense	2,219	—
Accrued other liabilities	7	20
Total	$ 4,603	$ 422

5. Commitments and Contingencies

Asset Purchase of OC-02

In October 2016, the Company entered into an asset purchase agreement pursuant to which the Company acquired the compound OC-02. The agreement provides for milestone payments of up to $37.0 million upon achievement of certain milestone events. The agreement also provides for royalty payments in the mid-single digit percentage on covered product net worldwide sales. The Company's obligation to pay royalties will terminate at the latter of patent expiration in each country or ten years. In addition, the Company is required to pay 15% of any (i) licensing revenue received that is related to OC-02 and (ii) revenue received from the sale of OC-02, up to a maximum aggregate amount of $10.0 million.

License Agreement

In October 2019, the Company entered into a non-exclusive patent license agreement (the License Agreement) with Pfizer, which granted the Company non-exclusive rights under Pfizer's patent rights covering varenicline tartrate to develop, manufacture, and commercialize the OC-01 varenicline product candidate. Under the terms of the License Agreement, the Company made an upfront payment to Pfizer of $5.0 million, which is included in research and development expense for the year ended December 31, 2019. If the Company successfully commercializes OC-01, it may be required to pay a single milestone payment in the very low double-digit millions and tiered royalties on net sales of OC-01 at percentages ranging from the mid-single digits to the mid-teens. The royalty obligation to Pfizer will commence upon the first commercial sale of OC-01 and will expire upon the later of (a) the expiration of all regulatory or data exclusivity granted to Pfizer in connection with varenicline in the United States; and (b) the expiration or abandonment of the last valid claims of the licensed patents.

Operating Lease Obligations

In January 2018, the Company entered a lease for office space under a non-cancelable operating lease with an expiration date of March 15, 2020, in Princeton, New Jersey. Rent expense is recorded on a straight-line basis over the term of the lease. The total lease payment over the life of the lease is $0.1 million. The remaining lease term was 0.2 years as of December 31, 2019.

In April 2019, the Company entered a lease for office space under a non-cancelable operating lease in Princeton, New Jersey, commencing on July 1, 2019, for a period of three years from the commencement date. Rent expense is recorded on a straight-line basis over the term of the lease. The total lease payment over the life of the lease is $0.9 million. The remaining lease term was 2.5 years as of December 31, 2019.
At the commencement date, the Company determined the amounts of the lease liability using a discount rate of 9%, which management determined represents the Company's incremental borrowing rate. Lease expense was $0.2 million and less than $0.1 million for the twelve months ended December 31, 2019 and December 31, 2018, respectively. Cash paid for amounts included in the measurement of the lease liability was $0.2 million and less than $0.1 million for the twelve months ended December 31, 2019 and December 31, 2018, respectively, and was included in cash flows from operating activities in the statements of cash flows.

The maturities of the lease liabilities under non-cancelable operating leases are as follows (in thousands):

As of December 31, 2018	**Amount**
2019	$ 59
2020	7
Total undiscounted cash flows	66
Less: imputed interest	(4)
Total operating lease liability	62
Less: current portion	(56)
Operating lease liability	$ 6

As of December 31, 2019	**Amount**
2020	$ 319
2021	316
2022	186
Total undiscounted cash flows	821
Less: imputed interest	(13)
Total operating lease liability	808
Less: current portion	(296)
Operating lease liability	$ 512

In January 2020 the Company amended the lease of one its office facilities in Princeton, New Jersey to include additional office space, with an expiration date of July 31, 2022. Total future minimum lease payments under this amendment are $0.4 million.

Contingencies and Indemnifications

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications, including for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims or been required to defend

any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

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

6. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the for the years ended December 31, 2019 and December 31, 2018 as it has incurred net losses since inception. In addition, the net deferred tax assets generated from net operating losses are fully offset by a valuation allowance as the Company believes it is not more likely than not that the benefit will be realized.

The Company's loss before provision for income taxes for the years ended December 31, 2019 and 2018 was as follows (in thousands):

	Year Ended December 31,	
	2019	**2018**
Domestic	$ (45,711)	$ (16,503)
International	—	—
Loss before provision for income taxes	$ (45,711)	$ (16,503)

The Company had an effective tax rate of 0% for the years ended December 31, 2019 and 2018. The provision for income taxes differs from the amount expected by applying the federal statutory rate to the loss before taxes as follows:

	Year Ended December 31,	
	2019	**2018**
Federal statutory income tax rate	21.0 %	21.0 %
State taxes (tax effected)	8.5 %	9.2 %
Research tax credit	3.3 %	2.6 %
Other permanent differences	(2.0)%	(0.2)%
Change in valuation allowance	(30.8)%	(32.6)%
Provision for income taxes	0.0%	0 %

The components of the Company's net deferred tax assets and liabilities as of December 31, 2019 and 2018, were as follows (in thousands):

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 12,454	$ 4,826
Credits	2,408	662
Tangible and intangible assets	1,977	269
Lease liability	227	—
Stock compensation	253	—
Other	36	57
Gross deferred tax assets	17,355	5,814
Less: Valuation allowance	(16,423)	(5,750)
Deferred tax assets, net of valuation allowance	932	64
Deferred tax liabilities:		
Prepaids	(708)	(64)
Right of use asset	(224)	—
Net deferred tax assets	$ —	$ —

Recognition of deferred tax assets is appropriate when realization of such assets is more likely than not. Based upon the weight of available evidence, which includes the Company's historical operating performance and the U.S. cumulative net losses in all prior periods, the Company has provided a valuation allowance against its U.S. deferred tax assets. The Company's valuation allowance increased by $10.7 million for the year ended December 31, 2019 and by $4.0 million for the year ended December 31, 2018.

As of December 31, 2019, the Company has U.S. federal and state net operating losses of $59.1 million and $60.7 million, respectively, which expire beginning in the year 2035. As of December 31, 2018, the Company had U.S. federal and state net operating losses of $22.8 million and $22.9 million, respectively, which expire beginning in the year 2035.

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

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

As of December 31, 2019 and 2018, the Company also had federal research and experimentation credit carryforwards of $2.1 million and $0.6 million, respectively, and state research and experimentation credit carryforwards of $0.4 and $0.1 million. The federal research and experimentation credit carryforwards expire beginning 2037. The California tax credit can be carried forward indefinitely.

As of December 31, 2019 and 2018, the Company had the following unrecognized tax benefits (in thousands):

	Year Ended December 31,	
	2019	2018
Balance at the beginning of the year	$ 1,989	$ 508
Additions based on tax positions related to current year	3,399	1,481
Balance at the end of the year	$ 5,388	$ 1,989

The reversal of the unrecognized tax benefits would not affect the Company's effective tax rate to the extent that it continues to maintain a full valuation allowance against its deferred tax assets. The Company does not expect any changes to uncertain tax benefits within the next twelve months.

The Company recognizes interest and penalties related to income tax matters as a component of income tax expense. No accrued interest and penalties have been recorded as of December 31, 2019 and 2018.

The Company files income tax returns in the U.S. federal, California and New Jersey jurisdictions. Due to the Company's net losses, its federal and state income tax returns are subject to examination for federal and state purposes since inception. As of December 31, 2019, there were no ongoing examinations.

7. Redeemable Convertible Preferred Stock

On February 15, 2019, the Company executed the Series B Preferred Stock Purchase Agreement to sell up to 6,581,590 shares of Series B redeemable convertible preferred stock. In February and April 2019, the Company received gross cash proceeds of $85.0 million and $8.0 million, respectively, from the sale of Series B redeemable convertible preferred stock.

On November 4, 2019, upon the closing of the IPO, all outstanding shares of redeemable convertible preferred stock were converted into an aggregate of 14,193,281 shares of the Company's common stock and $135.9 million of mezzanine equity was reclassified to common stock and additional paid-in capital. As of December 31, 2019, there were no shares of redeemable convertible preferred stock issued and outstanding.

8. Common Stock

The Company amended and restated its certificate of incorporation, effective November 4, 2019, in connection with the IPO. The amended and restated certificate of incorporation authorizes the Company to issue 1,000,000,000 shares of common stock, at a par value of $0.001 per share. Each share of common stock is entitled to one vote.

The Company reserved common stock shares for future issuance as of December 31, 2019 and 2018 as follows:

	December 31,	
	2019	**2018**
Conversion of Series A redeemable convertible preferred stock	—	7,611,691
Outstanding options under the 2016 Plan	2,748,434	1,376,084
Equity awards available for grants under the 2016 Plan	—	216,333
Outstanding options under the 2019 Plan	29,466	—
Unvested RSUs under the 2019 Plan	23,125	—
Equity awards available for grants under the 2019 Plan	2,747,047	—
Total	5,548,072	9,204,108

9. Equity Incentive Plans

In 2016, the Company established its 2016 Equity Incentive Plan (the "Plan") which provides for the granting of stock options to employees and consultants of the Company. Options granted under the Plan may be either incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to Company employees (including officers and directors who are also employees). NSOs may be granted to Company employees and consultants.

In October 2019, the Company's Board of Directors and stockholders approved the 2019 Equity Incentive Plan (the 2019 Plan), with an initial shares reserved of 2,700,000 shares of the Company's common stock plus 99,638 shares reserved but unissued under the 2016 Plan. The 2019 Plan provides for the granting of stock options, restricted stock, restricted stock units, stock appreciation rights, performance units, and performance shares to the Company's employees, directors, and others.

The exercise price of an ISO and NSO shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the board of directors. The exercise price of an ISO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, as determined by the board of directors. To date, outstanding options have a term of 10 years and generally vest monthly over a four-year period.

As of December 31, 2019, there were 2,747,047 common stock shares reserved for future grants under the 2019 Plan.

In October 2019, the Company's Board of Directors and stockholders also approved the 2019 Employee Stock Purchase Plan (the ESPP), which qualifies as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code, and pursuant to which 270,000 shares of common stock were reserved for future issuance. The ESPP is designed to enable eligible employees to purchase shares of the Company's common stock at a discount on a periodic basis through payroll deductions. There were no ESPP purchases during the year ended December 31, 2019.

Option activity under the Company's stock option plans is set forth below (in thousands, except share and per share data):

	Outstanding Awards			
	Number of Shares Underlying Outstanding Options	Weighted- Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2018	1,057,373	$ 1.00	9.85	$ 25
Options granted	318,711	1.02		
Outstanding at December 31, 2018	1,376,084	$ 1.00	8.90	$ 5,950
Options granted	1,446,823	8.01		
Options exercised	(11,703)	2.64		255
Options canceled	(33,304)	5.86		
Outstanding at December 31, 2019	$ 2,777,900	$ 4.59	8.73	$ 55,146
Shares vested and exercisable as of December 31, 2019	$ 1,108,041	$ 2.10	8.29	$ 24,757
Vested and expected to vest as of December 31, 2019	$ 2,777,900	$ 4.59	8.73	$ 55,146

During the years ended December 31, 2019 and 2018, the Company granted options with a weighted-average grant date fair value of $8.62 and $0.53 per share, respectively.

The fair value of options that vested during the years ended December 31, 2019 and 2018 was $2.5 million and $0.2 million, respectively.

As of December 31, 2019, the total unrecognized stock-based compensation expense for stock options was $9.4 million, which is expected to be recognized over a weighted-average period of 3.21 years.

In October 2019, the Company granted restricted stock units (RSUs) for 23,125 common stock shares that will vest one-third annually over three years, subject to continuing services to be provided to the Company. Grant date fair value was $16.00 per share, which is the common stock market price at the grant date. As of December 31, 2019, the total unrecognized stock-based compensation expense for RSUs was $0.3 million, which is expected to be recognized over a weighted-average period of 2.83 years.

Stock-Based Compensation Expense

The following table is a summary of stock compensation expense by function recognized (in thousands):

	Year Ended December 31,	
	2019	2018
Research and development	$ 579	$ 21
General and administrative	2,687	133
Total stock-based compensation	$ 3,266	$ 154

Fair Value of Options Granted

Prior to the IPO, the fair value of the Company's common stock underlying the stock options was determined by the Board of Directors with assistance from management and, in part, on input from an independent third-party valuation firm. The Board of Directors determined the fair value of common stock by considering a number of objective and subjective factors, including valuations of comparable companies, sales of convertible preferred stock, operating and financial performance, the lack of liquidity of the Company's common stock and the general and industry-specific economic outlook. Subsequent to the IPO, the fair value of the Company's common stock is based on the closing quoted market price of its common stock as reported by the NASDAQ Global Select Market on the date of grant.

In determining fair value of the stock options granted, the Company uses the Black-Scholes model, which requires the input of several assumptions. These assumptions include: estimating the length of time employees will retain their vested stock options before exercising them (expected term), the estimated volatility of the Company's common stock price over the expected term (expected volatility), risk-free interest rate and expected dividend rate. Changes in the following assumptions can materially affect the estimate of fair value and ultimately how much stock-based compensation expense is recognized.

Expected term. The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.

Expected volatility. The Company used an average historical stock price volatility of a peer group of comparable publicly traded companies in biotechnology and pharmaceutical related industries to be representative of its expected future stock price volatility, as the Company did not have any trading history for its common stock. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size and financial leverage of potential comparable companies. For each grant, the Company measured historical volatility over a period equivalent to the expected term.

Risk-free interest rate. The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equivalent to the expected term of the stock award.

Expected dividend rate. The Company has not paid and does not anticipate paying any dividends in the near future. Accordingly, the Company has estimated the dividend yield to be zero.

The fair value of options granted were calculated using the weighted average assumptions set forth below:

	Year Ended December 31,	
	2019	2018
Expected volatility	69.0 - 84.0%	52.5%
Risk-free interest rate	1.48% - 2.38%	2.49% - 2.80%
Dividend yield	0.00%	0.00%
Expected term	5.04 - 6.08 years	6.02 years

10. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Year Ended December 31,	
	2019	2018
Numerator:		
Net loss attributable to common stockholders	$ (45,711)	$ (16,503)
Denominator:		
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	4,585,146	1,411,966
Net loss per share attributable to common stockholders, basic and diluted	$ (9.97)	$ (11.69)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Year Ended December 31,	
	2019	2018
Series A redeemable convertible preferred stock	—	7,611,691
Options to purchase common stock	2,777,900	1,376,084
Unvested restricted stock units	23,125	—
Total	2,801,025	8,987,775

11. Quarterly Results of Operations Data (unaudited)

The following table sets forth our unaudited statement of operations and comprehensive loss data for each of the eight quarters in the two-year period ended December 31, 2019. The unaudited quarterly statement of operations and comprehensive loss data set forth below have been prepared on a basis consistent with the audited annual financial statements and include, in our opinion, all normal recurring adjustments necessary for a fair statement of the financial information contained in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future. The following quarterly financial data should be read in conjunction with our audited financial statements and the related notes.

Presented below is a summary of the unaudited quarterly financial information for the year ended December 31, 2019 (in thousands, except share and per share data):

	Three months ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Operating expenses:				
Research and development	$ 2,405	$ 8,101	$ 8,088	$ 15,034
General and administrative	1,605	3,132	3,809	5,127
Total operating expenses	4,010	11,233	11,897	20,161
Loss from operations	(4,010)	(11,233)	(11,897)	(20,161)
Interest income	250	503	400	437
Net loss and comprehensive loss	$ (3,760)	$ (10,730)	$ (11,497)	$ (19,724)
Basic and diluted net loss per share	$ (2.66)	$ (7.60)	$ (8.10)	$ (1.41)
Weighted average shares outstanding	1,411,966	1,412,354	1,419,064	13,993,730

Presented below is a summary of the unaudited quarterly financial information for the year ended December 31, 2018 (in thousands, except share and per share data):

	Three months ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Operating expenses:				
Research and development	$ 2,374	$ 2,261	$ 5,775	$ 3,345
General and administrative	626	735	916	704
Total operating expenses	3,000	2,996	6,691	4,049
Loss from operations	(3,000)	(2,996)	(6,691)	(4,049)
Interest income	66	70	59	38
Net loss and comprehensive loss	$ (2,934)	$ (2,926)	$ (6,632)	$ (4,011)
Basic and diluted net loss per share	$ (2.08)	$ (2.07)	$ (4.70)	$ (2.84)
Weighted average shares outstanding	1,411,966	1,411,966	1,411,966	1,411,966

Per share amounts for each quarter have been calculated separately. Accordingly, quarterly amounts may not add to annual amounts.

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following summary describes our common stock and preferred stock, as well as certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which have been filed as exhibits to this Annual Report on Form 10-K, as well as to the applicable provisions of the Delaware General Corporation Law.

Authorized Capital Stock

Our authorized capital stock consists of 1,000,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share. All outstanding shares of common stock are fully paid and non-assessable.

Common Stock

Our common stock is listed on the Nasdaq Global Select Market under the symbol "OYST." The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, MA 02021, and its telephone number is (800) 962-4284.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Preferred Stock

Under the terms of our amended and restated certificate of incorporation, our board of directors is authorized to issue, without any further vote or action by the stockholders, shares of preferred stock in one or more series and, with respect to each such series, to fix the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, of any wholly unissued series of Preferred Stock, including, without limitation, authority to fix by resolution or resolutions the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and

liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing.

The issuance of shares of preferred stock will affect, and may adversely affect, the rights of holders of common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until our board of directors determines the specific rights attached to that preferred stock. The effects of issuing additional preferred stock could include one or more of the following:

- restricting dividends on the common stock;
- diluting the voting power of the common stock;
- impairing the liquidation rights of the common stock; or
- delaying or preventing changes in control or management of our Company.

Preferred stock will be fully paid and nonassessable upon issuance.

Registration Rights of Certain Stockholders

Certain of our stockholders have registration rights under an investors' rights agreement, as amended (the "**Investors' Rights Agreement**"), between us and such stockholders. These stockholders (and certain of their permitted transferees), may request that we file registration statements under the Securities Act of 1933 and, upon such request and subject to minimum size and other conditions, we will be required to effect any such registration. We are generally obligated to bear the expenses, other than underwriting discounts and sales commissions, of all of these registrations. This summary does not purport to be complete and is qualified in its entirety by the provisions of the Investors' Rights Agreement, a copy of which has been filed as an exhibit to this Annual Report on Form 10-K.

Effect of Certain Provisions of our Amended and Restated Certificate of Incorporation and Bylaws and the Delaware Anti-Takeover Statute

Some provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could make the following transactions more difficult:

- acquisition of us by means of a tender offer;
- acquisition of us by means of a proxy contest or otherwise; or
- removal of our incumbent officers and directors.

Those provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids and to promote stability in our management. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Classified Board of Directors

Our amended and restated certificate of incorporation provides that our board of directors is divided into three classes, designated Class I, Class II, and Class III. Each class contains an equal number of directors, as nearly as possible, consisting of one-third of the total number of directors constituting our entire board of directors. The directors in each class are elected to serve for a three-year term, one class being elected each year by our stockholders. At each annual meeting of stockholders, successors to the class of directors whose term expires at that annual meeting will be elected for a three-year term.

Removal of Directors

Our amended and restated certificate of incorporation provides that stockholders may only remove a director for cause by a vote of at least a majority of the voting power of the issued and outstanding capital stock of our Company entitled to vote in the election of directors.

Director Vacancies

Vacancies and newly created directorships on our board of directors may be filled only by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the board of directors.

No Cumulative Voting

Our amended and restated certificate of incorporation provides that stockholders do not have the right to cumulate votes in the election of directors.

Special Meetings of Stockholders

Our amended and restated certificate of incorporation and amended and restated bylaws provides that, except as otherwise required by law, special meetings of the stockholders may be called only by an officer at the request of a majority of our board of directors, by the chairperson of our board of directors, or by our Chief Executive Officer.

Amending our Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation may be amended or altered in any manner provided by the DGCL. Our amended and restated bylaws may be adopted, amended, altered, or repealed by stockholders only upon approval of at least majority of the voting power of all the then outstanding shares of the common stock, except for any amendment of certain provisions, including those listed above, which would require the approval of a two-thirds majority of our then outstanding common stock. Additionally, our amended and restated certificate of incorporation provides that our bylaws may be amended, altered, or repealed by our board of directors.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval, except as required by the listing standards of Nasdaq, and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of our Company by means of a proxy contest, tender offer, merger or otherwise.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion 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 commenced, excluding for purposes of determining the voting stock outstanding, but not for determining the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also officers, and (ii) shares owned by 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

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by

written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person 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 a corporation’s outstanding voting stock.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-234416) of Oyster Point Pharma, Inc. of our report dated February 27, 2020 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 27, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey Nau, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oyster Point Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020

By: /s/ Jeffrey Nau
Jeffrey Nau, Ph.D., M.M.S.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel Lochner, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oyster Point Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020

By: /s/ Daniel Lochner
Daniel Lochner
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

PURSUANT TO

18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Oyster Point Pharma, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey Nau, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 27, 2020

By: /s/ Jeffrey Nau

Jeffrey Nau, Ph.D., M.M.S.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

PURSUANT TO

18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Oyster Point Pharma, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel Lochner, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 27, 2020

By: /s/ Daniel Lochner
Daniel Lochner
Chief Financial Officer
(Principal Financial and Accounting Officer)