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, 2020

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

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

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

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

As of the last business day of the most recently completed second fiscal quarter, the aggregate market value of the voting stock and non-voting common stock held by non-affiliates of the registrant was approximately $319.8 million based on the closing sale prices of such shares as reported on the NASDAQ Global Select Market.

As of February 1, 2021, the registrant had 25,909,694 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 2021 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, 2020.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and 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 the Company's 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 the Company's control and may cause its 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, such 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 the Company's clinical trials demonstrating safety and efficacy of its product candidates, and other positive results;
- the timing of initiation of the Company's future clinical trials, and the reporting of data from completed, current and future clinical trials and preclinical studies;
- plans relating to the clinical development of the Company's product candidates, including the size, number and disease areas to be evaluated;
- the size of the market opportunity and prevalence of dry eye disease for the Company's product candidates;
- plans relating to commercializing the Company's product candidates, if approved, including the geographic areas of focus and sales strategy;
- the success of competing therapies that are or may become available;
- the Company's estimates of the number of patients in the United States who suffer from dry eye disease and the number of patients that will enroll in its clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of the Company's product candidates;
- the timing, likelihood or scope of regulatory filings and approval for its product candidates;
- the Company's ability to obtain and maintain regulatory approval of its product candidates;
- the Company's plans relating to the further development and manufacturing of its product candidates, including additional indications for which it may pursue;
- the expected potential benefits of strategic collaborations with third parties and the Company's ability to attract collaborators with development, regulatory and commercialization expertise;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- the Company's plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- continued reliance on third parties to conduct additional clinical trials of the Company's product candidates, and for the manufacture and supply of product candidates, components for preclinical studies and clinical trials and products and components for commercialization of any approved products;
- the need to hire additional personnel, and the Company's ability to attract and retain such personnel;
- the potential effects of the novel strain coronavirus, or SARS-CoV-2 virus pandemic, on business, operations and clinical development timelines and plans;
- the accuracy of estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the Company's financial performance;
- the sufficiency of existing capital resources to fund future operating expenses and capital expenditure requirements;
- expectations regarding the period during which the Company will qualify as an emerging growth company under the JOBS Act; and
- the Company's anticipated use of its existing resources and proceeds from the initial and follow-on public offering.

The Company has based these forward-looking statements largely on its current expectations and projections about its business, the industry in which it operates and financial trends that it believes may affect 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, these forward-looking

statements should not be relied on as predictions of future events. The events and circumstances reflected in the Company's 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, the Company does 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 "the Company believes" and similar statements reflect its beliefs and opinions on the relevant subject. These statements are based upon information available to the Company as of the date of this Annual Report on Form 10-K, and while the Company believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and its statements should not be read to indicate that it has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

PART I

ITEM 1. BUSINESS

Overview

Oyster Point Pharma, Inc. (the Company) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases. The Company's lead product candidate OC-01 (varenicline) nasal spray, 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. OC-01 (varenicline) nasal spray'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. The Company has identified several additional indications, including some outside of ophthalmology, where this approach could provide a meaningful therapeutic benefit to patients.

On December 17, 2020, based on the safety and efficacy results from the Phase 2 MYSTIC, Phase 2b ONSET-1, and Phase 3 ONSET-2 clinical trials in over 1,000 subjects with dry eye disease, the Company submitted a 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease. The MYSTIC, ONSET-1 and ONSET-2 clinical trials showed statistically significant improvements in Schirmer's Score (an objective, reproducible, and quantifiable measure of natural tear film production), as compared to control, which was the primary endpoint in all studies. Key secondary endpoints in ONSET-1 and ONSET-2 included change from baseline in symptoms as assessed by eye dryness score. In both of these pivotal studies, there was statistically or nominally statistically significant improvement in symptom scores at Day 28, and in ONSET-2 as early as Day 14, as compared to control. All doses studied in the clinical trial program were well-tolerated with no serious drug related adverse events.

In addition, on November 30, 2020, the Company submitted to the FDA a protocol to initiate a clinical study in adult patients with neurotrophic keratopathy (NK), a degenerative disease characterized by decreased corneal sensitivity and poor corneal healing. The submission was made to the Company's Investigational New Drug (IND) application for OC-01 (varenicline) nasal spray in dry eye disease. NK is the second of a number of important potential indications the Company is evaluating for studying OC-01 (varenicline) nasal spray, illustrating the Company's commitment to treating unmet needs related to ocular surface diseases. Enrollment of the first patient in the OLYMPIA Phase 2 study in NK is planned for the first half of 2021.

Strategy

The Company's goal is to transform the treatment of dry eye disease and other ocular surface diseases by developing a broad portfolio of innovative therapies that target significant unmet medical needs. The Company intends to achieve this goal by pursuing the following key strategic objectives:

- **Completing development and obtaining approval of OC-01 (varenicline) nasal spray for the treatment of dry eye disease.** OC-01 (varenicline) nasal spray demonstrated statistically significant improvements (as compared to placebo) in signs of dry eye disease in the MYSTIC, ONSET-1 and ONSET-2 randomized, controlled clinical trials. In the ONSET-1 and ONSET-2 trials, there was statistically or nominally statistically significant improvement in symptom scores at Day 28, and in ONSET-2 as early as Day 14, as compared to placebo. The Company is not aware of another therapy that has shown statistically significant improvements in both signs and symptoms of dry eye disease in multiple registrational clinical trials. However, to date the Company's trials have been designed as randomized, masked, placebo-controlled clinical trials and, as such, the Company has not tested OC-01 (varenicline) nasal spray head-to-head with any other products or therapies, nor is it aware of any head-to-head results indicating that such other products or therapies could not have shown similar results. On December 17, 2020, based on the safety and efficacy results from the conducted clinical trials, the Company submitted a 505(b)(2) NDA to the FDA for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease.

- **Establishing specialty sales organization to commercialize OC-01 (varenicline) nasal spray in the United States.** If OC-01 (varenicline) nasal spray is approved for the treatment of the signs and symptoms of dry eye disease, the Company intends to commercialize its lead product candidate by deploying a specialty sales force at launch of approximately 150-200 field representatives targeting the top-prescribing ophthalmologists and optometrists in the United States. Given the importance of increasing awareness and educating patients with dry eye disease, the Company also anticipates deploying focused direct-to-consumer marketing campaigns for OC-01 (varenicline) nasal spray. The Company anticipates that this sales organization could also support the commercialization of additional product candidates treating ocular diseases.

- **Maximizing value of OC-01 (varenicline) nasal spray and the Company's other product candidates outside the United States.** With more than 300 million additional dry eye disease patients outside of the United States, the Company believes there is a significant commercial opportunity for its product candidates internationally. To address these markets, it may seek one or more partners with regional capabilities and infrastructure to support and potentially accelerate the clinical development and commercialization of the Company's product candidates, if approved, in such geographies.

- **Developing OC-01 (varenicline) nasal spray for additional indications associated with and beyond dry eye disease.** Based on the fundamental role of natural tear film in ocular surface health, the Company plans to pursue development of OC-01 (varenicline) nasal spray in other indications where this equilibrium is disturbed. First, the Company submitted to the FDA a protocol to initiate a clinical study in adult patients with NK, 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, the Company believes that its 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 dry eye disease associated with contact lens intolerance. In addition, based on the unique characteristics of this product candidate, the Company sees 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.

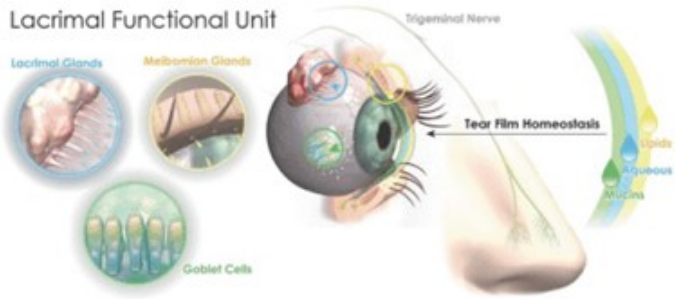
- **Leveraging the capabilities of the Company's experienced discovery and development team and its nAChR domain expertise to continue expanding pipeline of product candidates.** The Company has studied a second nAChR agonist product candidate OC-02 (simpinicline) in two Phase 2b clinical trials for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

- **Selectively evaluating external opportunities to expand the scope of the Company's pipeline or product offerings.** The Company may pursue collaboration, acquisition or in-licensing of product candidates, particularly in its core disease area of ocular surface diseases.

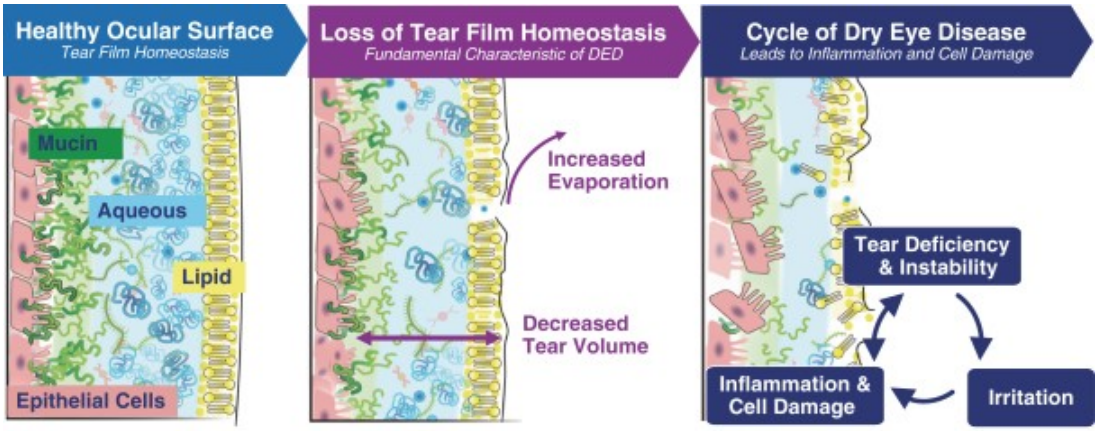
Dry Eye Disease Overview

Dry eye disease 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 dry eye disease are also more susceptible to eye infections and damage to the surface of the eye (cornea). Dry eye disease 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. It can affect daily life, including reading and driving at night and has been associated with depression and migraines. Dry eye disease can also limit patients' ability to tolerate contact lenses and can impact 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 dry eye disease. Animal models of dry eye disease have consistently shown that disrupting the parasympathetic input to the lacrimal gland causes decrease in tear film production resulting in a corresponding increase in corneal fluorescein staining and inflammatory markers. Re-establishment of tear film production normalizes staining and inflammatory markers. Chronic disruption and instability of the tear film results in irritation, inflammation, and ultimately cellular damage. Chronic symptoms of dry eye disease 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 dry eye disease, as well as therapies in clinical development, target inflammation further down the dry eye disease continuum. The Company believes these therapies have only been studied in patients with moderate to severe dry eye disease and do not address the loss of tear film homeostasis, the fundamental characteristic of dry eye disease. The Company's lead product candidate OC-01 (varenicline) nasal spray 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 dry eye disease.



Market opportunity in dry eye disease

Dry eye disease is highly prevalent and growing, affecting more than 340 million people globally based on the studies conducted in 2016. In the United States, dry eye disease 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 dry eye disease continues to grow due to an aging population, increase in autoimmune diseases, contact lens wear and digital screen time. Although dry eye disease is one of the most common reasons people visit eye care practitioners (ECPs) in the United States, it is estimated that only 16 million adults have been diagnosed with dry eye disease by an ECP, which the Company believes is due in part to lack of education and insufficient awareness on the part of the patient.

Despite the number of patients diagnosed with dry eye disease, the Company estimates that only 7 million patients have started a prescription treatment regimen which the Company believes is based at least in part on a lack of treatment options that are suitable for chronic use. In a survey the Company commissioned in June 2017 (the ECP Survey) ECPs were generally neutral or dissatisfied with their treatment options for patients with dry eye disease. 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 dry eye disease and are familiar with, or prescribe, currently available prescription therapies. In the ECP Survey, the Company asked ECPs to select whether they completely disagreed, were neutral or completely agreed with the statement that they "can successfully treat all dry eye disease 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 another survey, conducted among the 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. The Company believes the results in the survey reflect why only 2 million patients are on a prescription therapy at any given time. Despite the small percentage of dry eye disease patients on prescription therapy, Restasis (marketed by Allergan) had U.S. sales in 2019 of $1.2 billion.

Current treatment options and their limitations

Dry eye disease is primarily treated with a variety of over-the-counter eye drops, often referred to as "artificial tears," and four FDA-approved prescription eye drop therapies: Restasis®, Xiidra® (marketed by Novartis), Cequa™ (marketed by Sun Pharma) and Eysuvis™ (marketed by Kala Pharmaceuticals). 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 dry eye disease, address chronic inflammation associated with dry eye disease. Eysuvis™, a corticosteroid which has been approved for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease, addresses acute inflammation. Other products used by patients suffering from dry eye disease include ointments, gels, warm compresses, omega-3 fatty acid supplements and a number of medical devices. Unfortunately, all currently approved treatment options for dry eye disease have significant limitations, which include:

- *Mechanisms of action only address inflammation.* Currently approved therapies only target inflammation for moderate to severe dry eye disease; 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 dry eye disease, the loss of tear film homeostasis, the Company estimates 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. The Company believes this delayed onset of action may hinder compliance and in turn may limit the benefit that patients derive from such treatments.

- *Tolerability and compliance issues.* Currently approved pharmaceutical therapies for dry eye disease 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 may result in reduced compliance. Corticosteroids are limited based on known complications of glaucoma and damage to the optic nerve as well as delayed wound healing of the cornea.

To address these limitations and the high unmet need expressed by patients, ECPs and payors, the Company has been developing OC-01 (varenicline) nasal spray, which it believes, if approved, has the potential to become the new standard of care for dry eye disease. However, there is no guarantee that it will provide results comparable to existing treatments. OC-01 (varenicline) nasal spray's highly differentiated mechanism of action, as shown in preclinical and clinical studies, is designed to re-establish tear film homeostasis, addressing the fundamental disease process, regardless of stage of disease or underlying cause. The Company is 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 (varenicline) nasal spray 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 (varenicline) 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 (varenicline) nasal spray. The Company believes OC-01 (varenicline) nasal spray, 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.

Company's approach: activating the trigeminal parasympathetic pathway to promote natural tear film production

The Company's novel treatment approach for dry eye disease 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 (TPP)

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.

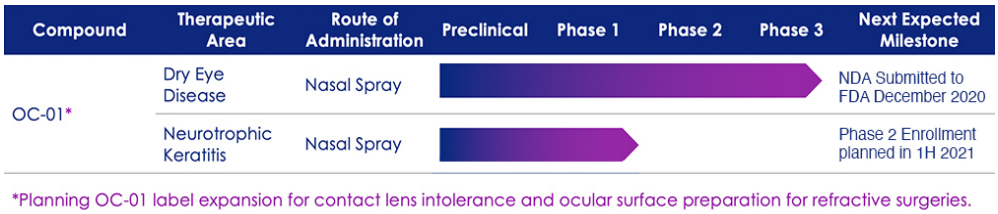
The Company refers to the communication between the trigeminal nerve and the LFU as the TPP. The efferent paths (away from the nose) of the TPP proceed from the superior salivary nucleus along the facial nerve to the geniculate ganglion and from there through the greater superficial petrosal nerve via 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

The Company's approach to dry eye disease relies on a pharmaceutical stimulation of a class of receptors called 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).

The Company's product candidate OC-01 (varenicline) nasal spray contains an active pharmaceutical ingredient (API) that is highly selective to the nAChRs that activate the TPP. The Company believes this is the first application of nAChR agonists to be delivered nasally to stimulate the nerves of the PNS. Additionally, it has found that OC-01 (varenicline) nasal spray'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.

Product Candidates



OC-01 (varenicline) nasal spray for dry eye disease

The Company's lead product candidate OC-01 (varenicline) nasal spray is being developed as a nasal spray to treat the signs and symptoms of dry eye disease. 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 (varenicline) nasal spray 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 was 1.2 mg/ml, approximately 7.5% of the systemic exposure of a single maintenance dose of Chantix® (1 mg) on a normalized dosing basis.

OC-01 (varenicline) nasal spray's novel mechanism of action

OC-01 (varenicline) nasal spray's novel mechanism of action, as shown in preclinical and clinical studies, 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. The Company believes that the development of OC-01 (varenicline) as a nasal spray represents the first pharmacological treatment approach for dry eye disease targeting the nerves that control the LFU. OC-01 (varenicline), 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 (varenicline) 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 OC-01 (varenicline) 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).

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

Development program for OC-01 (varenicline) nasal spray

In October 2018, the Company 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 (varenicline) nasal spray in 182 subjects with dry eye disease in the United States.

The Company 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

(varenicline) nasal spray and Chantix®, it will allow the Company to reference certain FDA conclusions regarding the safety of varenicline from the Agency's review of the Chantix® NDA. Otherwise, additional data may be needed to support the NDA and potential approval of OC-01 (varenicline) nasal spray.

In January 2020, the Company reported results from MYSTIC, a randomized, single-masked, vehicle-controlled Phase 2 clinical trial that evaluated the safety and efficacy of OC-01 (varenicline) nasal spray in 123 subjects with dry eye disease. The goal of this study was to assess the safety and efficacy of twice daily dosing of OC-01 (varenicline) nasal spray administered for 84 days. Although the study adds to the totality of the data in support of the efficacy of OC-01 (varenicline) nasal spray in subjects with dry eye disease, the MYSTIC data is only being used to support the safety of OC-01 (varenicline) nasal spray in terms of the NDA submission.

Following ONSET-1, the Company initiated a Phase 3 registrational clinical trial (ONSET-2) in July 2019 and released positive top line the results of the study in May 2020. During the ONSET-2 Phase 3 clinical trial conducted in 758 subjects, OC-01 (varenicline) nasal spray demonstrated a statistically significant improvement (as compared to placebo) in signs of dry eye disease in both the 0.6 mg/ml and 1.2 mg/ml dose groups and statistically significant improvements (as compared to placebo) in both signs and symptoms of dry eye disease in the 1.2 mg/ml dose group.

Clinical Trials Results

In the description of the Company's 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 (varenicline) nasal spray demonstrated statistically significant improvements in both signs and symptoms of dry eye disease. The study compared three different doses of OC-01 (varenicline) nasal spray 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 dry eye disease as measured by EDS at Weeks 3 and 4. The Company 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, which is a registered trademark of Ora, Inc., (or 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 (varenicline) nasal spray 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 the Company cannot guarantee that the FDA will grant marketing approval for OC-01 (varenicline) nasal spray 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 dry eye disease. 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 (varenicline) nasal spray 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.

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 (varenicline) nasal spray 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).

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). 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 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.

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 (varenicline) nasal spray compared to subjects treated with placebo.

ONSET-1 was not designed or powered to assess corneal fluorescein staining, although the Company 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 (varenicline) nasal spray in central, superior, and temporal staining as compared to placebo. The Company believes 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 (varenicline) nasal spray in total, central, temporal, inferior, and nasal staining as compared to placebo.

OC-01 (varenicline) nasal spray 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. No subjects in the placebo group reported either sneezing or cough.

ZEN: Phase 1 comparative pharmacokinetic clinical trial results

The Company completed a comparative pharmacokinetic "bridge" trial (ZEN) where it evaluated the relative bioavailability of varenicline administered as a nasal spray (OC-01) compared to varenicline administered orally. The Company 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 (varenicline) administered as a nasal spray compared to varenicline administered orally.

Top-line results indicated that administration of 2 sprays (one in each nostril) of OC-01 (varenicline) nasal spray is detected in plasma by 5 minutes, and generally achieves peak concentration within 2 hours, with a mean Cmax of 0.34 ng/mL. OC-01 (varenicline) nasal spray administered intranasally as a 60 mcg per 50-µL spray into each nostril resulted in a varenicline mean Cmax of 0.34 ng/mL and AUC0-inf was 7.46 h*ng/mL. The results from the bioavailability study demonstrate that total systemic exposure of 0.12 mg administered intranasally was 7.5% compared to a 1 mg oral dose of varenicline.

The study demonstrated that OC-01(varenicline) 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.

This trial could allow the Company 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 the Company's 505(b)(2) NDA submission would be considered scientifically justified if exposure levels following nasal spray administration of its 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 (varenicline) nasal spray 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 (varenicline) 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 (varenicline) 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.

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 7.9-13.4; $p<0.05$), 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 7.9-14.0; $p<0.05$). Results were statistically significant in both the observed and Last Observation Carried Forward analyses.

OC-01 (varenicline) nasal spray 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 (varenicline) 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 (varenicline) nasal spray groups and resolved by the next visit.

ONSET-2: Phase 3 clinical trial results

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 (varenicline) in approximately 750 subjects with dry eye disease in the United States.

The goal of this study was to assess the safety and efficacy of twice daily dosing of OC-01 (varenicline) nasal spray at the two different dose levels, administered for 4 weeks. The pre-specified primary endpoint was the percentage of subjects gaining at least 10mm on the Schirmer's Score as compared to control. Pre-specified secondary endpoints included mean change in Schirmer's Score (sign) at Week 4, patient-reported symptoms of DED as measured by EDS in the normal clinic environment at Weeks 1, 2 and 4, as well as in a CAE®, a low humidity, high airflow environment at Week 4. The study also measured corneal fluorescein staining in both dose groups at Week 4. Subjects will continue to be evaluated post-treatment in a long-term follow up through 12 months.

A statistically significant improvement in the primary endpoint of percentage of subjects gaining at least 10 mm in Schirmer's Score at Week 4 was observed in both doses tested as compared to control as shown in the figure below. In the group of subjects treated with the 0.6 mg/ml dose, the percentage of subjects gaining at least 10mm on Schirmer's Score was 44% ($p<0.0001$ vs. control). In the 1.2 mg/ml dose group, the percentage of subjects gaining at least 10mm on Schirmer's Score was 47% ($p<0.0001$ vs. control). The percentage of subjects gaining at least 10mm on Schirmer's Score in the control group was 26%.

Additionally, consistent with the 0.6 mg/ml and 1.2 mg/ml results observed in ONSET-1, there was a statistically significant improvement in mean change in Schirmer's Score at Week 4 in both doses tested as compared to control as shown in the figure below. In the group of subjects treated with the 0.6 mg/ml dose, at Week 4 the mean change from baseline in Schirmer's Score was 11.0 mm ($p<0.0001$ vs. control). In the group of subjects treated with the 1.2 mg/ml dose, at Week 4 the mean change from baseline on Schirmer's Score was 11.2 mm ($p<0.0001$ vs. control). Mean change from baseline on Schirmer's Score in the control group was 5.9 mm.

OC-01 (varenicline) nasal spray was well-tolerated in ONSET-2 and the adverse event data collected to date was consistent with the results of ONSET-1. The most common adverse event experienced in the treatment groups was sneeze after administration, which occurred with 50% of nasal spray administrations. These adverse events were predominantly transient, with the majority of sneezes occurring within the first minute following administration, and mild in severity. There were no reports of serious adverse events determined to be related to nasal administration. The number of subjects with treatment emergent adverse events related to study drug leading to treatment discontinuation was 2% or less in either treatment group.

After conducting further post-hoc analyses of the data, the Company believes that there is a treatment benefit in the 1.2 mg/ml dose group that was not captured with the statistical method used for analysis of the endpoint. The statistical power for assessing this endpoint was negatively impacted by a decrease in the sample size, which the Company believes was due in part to subjects being unable to be assessed as a result of the SARS-CoV-2 pandemic. In addition, there were a number of subjects that did not meet the criteria for treatment in the CAE®, thereby further reducing statistical power. Treatments in the CAE® are only administered if a participant reports an Ocular Discomfort score ≥ 3 at two or more consecutive time points in at least one eye during CAE® exposure, for participants with an Ocular Discomfort rating of 3 at baseline. Participants with an Ocular Discomfort rating of 4 at baseline for an eye must report an Ocular Discomfort rating of 4 for two additional consecutive measurements for that eye, not including the baseline measurement.

OLYMPIA: Neurotrophic keratopathy (NK) clinical trial study

Leveraging its nAChR domain expertise, the Company continues to explore the development of OC-01 (varenicline) nasal spray for a number of potential indications and uses associated with and beyond dry eye disease including NK, dry eye associated with contact lens intolerance, and ocular surface treatment for refractive surgeries.

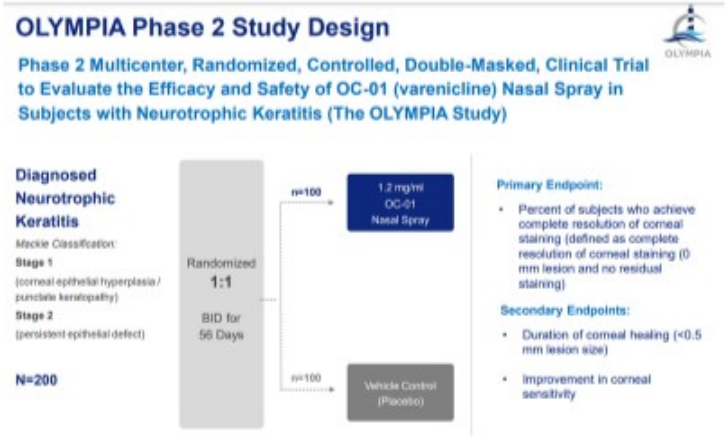
NK is caused when the nerves that supply the cornea cannot function properly. NK reduces sensitivity of the cornea. When the cornea senses stimulation or pressure, the eyelids will close and tears will be produced to protect the cornea and the eye. Because these nerves do not function properly in NK, 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. The Company believes 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 NK study design, OLYMPIA, is included below:

OLYMPIA Study Design



Regulatory

The Company 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 (varenicline) nasal spray. Based on this feedback, the Company initiated ONSET-2, a 750-subject, multicenter, randomized, double-masked, placebo-controlled Phase 3 trial, in July 2019. The objective of this study was to evaluate the safety and efficacy of OC-01 (varenicline) nasal spray at 0.6 mg/ml and 1.2 mg/ml doses as compared to placebo for the treatment of the signs and symptoms of dry eye disease. 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, allowed the Company to achieve the minimum number of subjects for safety-monitoring purposes. This study had similar eligibility criteria and design to ONSET-1.

On November 30, 2020, the Company submitted to the FDA a protocol to initiate a clinical study in adult patients with NK, a degenerative disease characterized by decreased corneal sensitivity and poor corneal healing. The submission was made to the Company's IND for OC-01 (varenicline) nasal spray in dry eye disease. NK is the second of a number of important potential indications the Company is evaluating for studying OC-01 (varenicline) nasal spray, illustrating the Company's commitment to treating unmet needs related to ocular diseases. Enrollment of the first patient in the OLYMPIA Phase 2 study in NK is planned for the first half of 2021.

Varenicline tartrate is currently marketed by Pfizer in the United States under the trade name Chantix® as an aid to smoking cessation treatment. The Company has submitted a 505(b)(2) NDA for OC-01 (varenicline) nasal spray, relying in part upon certain FDA conclusions regarding the safety of varenicline from the Agency’s review of the Chantix® NDA.

On December 17, 2020, based on the safety and efficacy results from the Phase 1 Zen, Phase 2 MYSTIC, Phase 2b ONSET-1 and Phase 3 ONSET-2 clinical trials in over 1,000 subjects with dry eye disease, the Company submitted a 505(b)(2) NDA to the FDA for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, significant competition and an emphasis on intellectual property. The Company faces 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 the Company successfully develops and commercializes will compete with currently approved therapies and new therapies that may become available in the future. The Company believes that the key competitive factors affecting the success of any of its 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 dry eye disease in the United States. The most commonly used treatments for dry eye disease in the United States are over-the-counter eye drops, often referred to as "artificial tears," and four FDA-approved prescription eye drop therapies: Restasis®, Xiidra®, Cequa™ and Eysuvis™. 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 dry eye disease. Eysuvis™ provides temporary relief of the signs and symptoms of dry eye disease, which may include the management of dry eye disease flares. Other treatment options include ointments, gels, warm compresses, omega-3 fatty acid supplements and a number of medical devices. The Company is aware of many other companies developing therapies for dry eye disease, including Aerie Pharmaceuticals, Alcon, Aldeyra Therapeutics, Allergan, Azura Ophthalmics, Bausch Health (Novaliq), HanAll BioPharma, Johnson & Johnson, Mitotech, Novartis, Parion Sciences, ReGenTree, Silk Technologies, Sylentis, TopiVert Pharma, and TearSolutions.

Many of the companies against which the Company 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. 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 the Company 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, the Company's programs.

Sales and Marketing

In light of the Company's stage of development, it has not yet established a commercial organization or distribution capabilities. If OC-01(varenicline) nasal spray receives regulatory approval, the Company plans to commercialize it in the United States with a focused, specialty sales force that could consist of its own employees, outsourced sales professionals, or a hybrid model utilizing both internal and external resources. In anticipation of the FDA PDUFA date, the Company projects hiring approximately 150 to 200 sales representatives that will call on top-prescribing ophthalmologists and optometrists. The Company believes an organization of this size would allow it 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 dry eye disease, the Company also anticipates deploying focused direct-to-consumer marketing campaigns for OC-01 (varenicline) nasal spray. The Company's sales force could also support the commercialization of additional product candidates treating ocular diseases. The Company also expects to explore commercialization of OC-01 (varenicline) nasal spray 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

The Company does not currently own or operate facilities for manufacturing, storing, distributing or testing of its product candidates. It relies, and expects to continue to rely for the foreseeable future, on third party contract manufacturing organizations (CMOs), to manufacture and supply its preclinical and clinical materials to be used during the development of its product candidates.

The product candidate OC-01 (varenicline) nasal spray 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. The Company believes the amounts of the API as well as OC-01 (varenicline) nasal spray it currently has on hand are sufficient to complete future clinical studies. Additional cGMP varenicline API, nasal pumps and bottle components and manufacturing capacity campaigns are available in adequate quantities to ensure full supply for the Company's commercial scale-up, validation and commercial launch activities if OC-01 (varenicline) nasal spray is approved.

Although, the Company currently relies on separate, single CMO as its sole supplier for the OC-01 API and a single CMO to manufacture OC-01 (varenicline) nasal spray, it is also in the process of identifying and qualifying additional manufacturers to provide OC-01 API and drug product manufacturing to support the submission of a post approval change to the NDA, if approved, for OC-01 (varenicline) nasal spray for commercial supply or to support future clinical studies. The Company expects that it can qualify an OC-01 API manufacturer and qualify and transfer the process to a selected CMO. Additionally, the drug product manufacturing is a simple compounding and micro controlled filling operation that could also be transferred to additional CMOs as necessary.

The Company's third party service providers, third party supply chain providers, their facilities and the OC-01 (varenicline) nasal spray used in 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 the Company can manufacture commercial products. The Company's third party manufacturers are also subject to periodic inspections of their facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of OC-01 (varenicline) nasal spray to assess compliance with applicable regulations. The Company's failure, or the failure to its third party providers and supply chain providers, to comply with such statutory and regulatory requirements could subject the Company 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 or future commercial supplies of OC-01 (varenicline) nasal spray or the Company's 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

Patents

The Company's success depends in part on its ability to obtain and maintain proprietary protection for its product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing its proprietary rights. The Company's patent portfolio is intended to cover its product candidates and components thereof, their methods of use and processes for their manufacture, the Company's proprietary reagents and assays and any other inventions that are commercially important to its business. It also relies on trade secret protection of confidential information and know-how relating to the Company's proprietary technology, platforms and product candidates.

The Company's patent portfolio as of December 31, 2020 contained approximately 16 issued and unexpired United States (U.S.) patents, three pending non-provisional U.S. patent applications, and two pending patent cooperation treaty (PCT) applications that are solely owned by the Company 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, the Company has selectively and strategically abandoned certain of its patent applications in countries with smaller markets and/or a history of weak patent enforcement record. With respect to its candidate OC-01 (varenicline) nasal spray, the Company's patents and patent applications include methods of treatment and pharmaceutical formulations. With respect to the Company's candidate OC-02, the patents and patent applications cover chemical composition, synthesis and preparation, formulations, and methods of treatment. The Company continues to seek to maximize the scope of its patent protection for all its programs. The Company has 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.

Licenses

The Company is party to a non-exclusive patent license agreement (the License Agreement) with Pfizer. Pursuant to the License Agreement, Pfizer granted the Company 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 OC-01 varenicline product candidate for the treatment of any ophthalmic disease or condition via nasal administration in the United States. Under the License Agreement, the Company was obligated to make upfront payment to Pfizer, as well as potentially additional milestone payments and royalties upon achievement of certain milestones. For further discussion, refer to Item 15—Note 9, *Commitments and Contingencies.*

Regulatory Pathway

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.

The Company's 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;
- payment of user fees for FDA review of the NDA;
- 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;
- 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.

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 the Company interprets 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 NDA 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. The Company relies, and expects to continue to rely, on third parties for the production of clinical and commercial quantities of its 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, 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 laws, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or qui tam actions and civil monetary penalties laws, 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 FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- 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, state and local laws that require the registration of pharmaceutical sales representatives;

- 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;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding their payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiology assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- 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, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates," that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous 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 pharmaceutical companies, among others, 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, 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 the Company's 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, the Company may apply for restoration of patent term for its 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 is currently 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. These changes will primarily be introduced under the Clinical Trials Regulation EU No 536/2014, which also aims to harmonize the rules for conducting clinical trials across the EU. In the meantime, Clinical Trials Directive 2001/20/EC, and national implementing legislation, 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 the Company's products will depend, in part, on the extent to which its 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 the Company's 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. The Company may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of its products. As a result, the coverage determination process is often a time-consuming and costly process that will require the Company to provide scientific and clinical support for the use of its products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

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 the Company receives marketing approval. However, any negotiated prices for the Company's products covered by a Part D prescription drug plan likely will be lower than the prices it 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.

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 the Company's 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 ACA was passed which substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact 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.

There remain judicial, Congressional and executive branch challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed several 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, several 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 (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." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. 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. The United States Supreme Court is currently reviewing this case, although it is unclear when the Supreme Court will make a decision. Although the United States Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is also unclear how such litigation, other efforts to repeal and replace the ACA and the healthcare reform measures of the Biden administration will impact the ACA and the Company's business.

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 2030 unless additional Congressional action is taken. However, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) and other SARS-CoV-2 relief legislation have suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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 laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for the Company's drugs, if approved, and accordingly, the Company's 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's budget proposal for the fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. In addition, the Trump administration previously released a "Blueprint" to lower prescription drug prices and reduce out-of-pocket costs of drugs that contained 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. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA also released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. In addition, on November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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.

The Company expects that additional healthcare reform measures may be adopted in the future, particularly in response to the recent presidential election. Further, it is possible that additional governmental action is taken in response to the SARS-CoV-2 pandemic.

Research and Development

The Company recognized $39.8 million and $33.6 million of research and development expenses during the years ended December 31, 2020 and 2019, respectively.

Human Capital Management

As of December 31, 2020, the Company had 62 full-time employees based in the United States, building key capabilities by adding 35 employees since 2019. This talent was hired to support and extend the Company's clinical and preclinical pipeline, as well as develop organizational strength and infrastructure in CMC, selling, general and administrative functions. None of the Company's employees are represented by a labor union or are covered under a collective bargaining agreement.

In response to the SARS-CoV-2 virus pandemic, the Company implemented changes that it determined to be in the best interest of its employees, as well as the communities in which the Company operates, and which comply with government regulations. The implemented changes included having employees work remotely while management monitored and implemented additional safety measures on-site in preparation for an eventual return to the office.

The Company expects to continue to grow its organizational footprint in 2021 with a focus on expanding its sales force in connection with the anticipated commercial launch of its main candidate OC-01 (varenicline) nasal spray in the fourth quarter of 2021, if approved by the FDA. In anticipation of the FDA PDUFA date, the Company projects hiring approximately 150 to 200 sales representatives, in addition to bolstering management and support functions. The Company will continue to evaluate the business needs and market opportunities, balancing in house expertise and core competencies with outsourced capacity. Currently, the Company outsources much of its preclinical and clinical development, as well as manufacturing to contract manufacturers and third party providers.

Drug development and commercialization requires deep expertise across a broad array of disciplines. Pharmaceutical companies of all sizes compete for a limited number of qualified applicants to fill specialized positions. To attract qualified candidates, the Company offers an attractive total rewards package, consisting of base salary, cash bonus, a comprehensive benefit package, equity compensation, and 401(k) plan. Bonus opportunities and equity compensation increase as a percentage of total compensation based on level of responsibility, and actual bonus awards are based on performance.

Corporate Information

The Company files electronically with the SEC its 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. The Company makes available on its website at www.oysterpointrx.com, free of charge, copies of these reports, as soon as reasonably practicable after such reports are filed electronically with, or furnished to, the SEC. The Company also routinely posts press releases, presentations, webcasts, and other information regarding the Company on its website. The information posted on the Company's website is not a part of this Annual Report on Form 10-K.

Oyster Point, the Oyster Point logo and its 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 the Company's 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 the Company will not assert, to the fullest extent under applicable law, its rights or the rights of the applicable licensor to these trademarks and trade names. The Company does not intend its use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of the Company by, any other entity.

ITEM 1A. RISK FACTORS

Investing in the Company's 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 were filed and will be filed with the SEC, in evaluating the Company and its business. Additional risks and uncertainties not presently known to or that are currently seen as immaterial may also harm Company's business. If any of these risks occur, business, growth prospects, operating results and financial condition could be materially and adversely affected, the trading price of the Company's common stock could decline and investors could lose part or all of their investment.

Summary Risk Factors

- The Company is a clinical stage biopharmaceutical company with limited operating history and significant losses and negative cash flow, which may make it difficult for investors to evaluate its current business and predict its future success and viability.
- The Company's business depends entirely on the successful development and commercialization of its product candidates, and is highly dependent on success of its main lead candidate OC-01 (varenicline) nasal spray for the treatment of dry eye disease.
- The Company's lead product candidate OC-01 (varenicline) nasal spray is based on API that is already on the market, which exposes the Company to additional risks. In addition, OC-01 (varenicline) nasal spray uses a novel and unproven therapeutic approach and mechanism of action, and therefore its efficacy and safety are difficult to predict, and there is no guarantee that OC-01 (varenicline) nasal spray or any other product candidates will be approved by the FDA.
- Drug development is a highly uncertain undertaking and involves a substantial degree of risk; in addition, clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. The outcome of preclinical testing and earlier clinical trials may not be predictive of the success of later clinical trials, and interim, topline and preliminary data from clinical trials may change as more data becomes available.
- If the Company experiences delays or difficulties in the enrollment of subjects in clinical trials, its receipt of necessary regulatory approvals could be delayed or prevented, the Company may be unable to obtain required regulatory approvals, and therefore be unable to commercialize its product candidates on a timely basis or at all.
- The Company's business, operations and clinical development timelines and plans could be adversely affected by the effects of health epidemics, including the SARS-CoV-2 virus pandemic.
- If the Company engages in acquisitions, in-licensing or strategic partnerships, this may increase its capital requirements, dilute stockholders, cause it to incur debt or assume contingent liabilities and subject the Company to other risks.
- The Company is subject to government regulation and contractual obligations related to privacy, security, and data protection, and its actual or perceived failure to comply with such obligations could harm its business. Additionally, cyber-attacks or information security breaches that could compromise the Company’s computer systems and data, or those of its third party partners, contractors or consultants, could expose the Company to liability, affect its reputation and otherwise harm the business.
- Changes in U.S. tax law may materially adversely affect the Company's financial condition, results of operations and cash flows.
- The commercial success of the Company's products is subject to a number of risks, including risks associated with scaling up manufacturing to commercial scale, marketing the Company's product candidates internationally and the availability and sufficiency of third party payor coverage and reimbursement.
- Even if the Company obtains regulatory approval for any of its product candidates, it 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.
- The Company faces significant competition, and the Company's product candidates may, if approved, compete with existing branded, generic and off-label products.
- The Company is subject to risks of litigation, including securities litigation. Further, if product liability lawsuits are brought against the Company, it may incur substantial liabilities and may be required to limit commercialization of its products.
- If the Company is unable to obtain and maintain patent protection for its technology and products for any reason, or if the scope of the patent protection obtained in any market is not sufficiently broad, the Company may not be able to compete effectively in its markets.
- Third party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate the Company's patents or other proprietary rights, may delay or prevent the development and commercialization of OC-01 (varenicline) nasal spray and other product candidates.

- The Company may become involved in lawsuits to protect or enforce its patents, the patents of any licensors or its other intellectual property rights, which could be expensive or even cost-prohibitive, time consuming, and unsuccessful given the uncertainty of litigation.
- The Company's future reliance on third parties may require the Company to share its trade secrets, which increases the possibility that a competitor will discover them or that the Company's trade secrets will be misappropriated or disclosed.
- The Company may be subject to claims that its employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.
- Intellectual property rights do not necessarily address all potential threats to its competitive advantage.
- If the Company's future trademarks and trade names are not adequately protected, then it may not be able to build name recognition in markets of interest and its business may be adversely affected.
- If the Company fails to comply with its obligations under any license, collaboration or other agreements, such agreements may be terminated, the Company may be required to pay damages and it could lose intellectual property rights that are necessary for developing and protecting its product candidates; in addition, collaboration or partnership arrangements that the Company may enter into in the future may not be successful.
- If the FDA does not conclude that OC-01 (varenicline) nasal spray 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 the Company expects, 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.
- The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If the Company is ultimately unable to obtain regulatory approval for its product candidates, it will be unable to generate product revenue and its business will be substantially harmed.
- The Company's 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.
- If the Company fails to comply with environmental, health and safety laws and regulations, it could become subject to fines or penalties or incur costs that could have a material adverse effect on its business.
- Obtaining and maintaining regulatory approval of the Company's product candidates in one jurisdiction does not mean that the Company will be successful in obtaining regulatory approval of its product candidates in other jurisdictions.
- The Company's business activities are subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries in which it operates, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations.
- Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could prevent new products and services from being developed or commercialized in a timely manner.
- The Company relies on third parties to conduct its clinical trials and for the production of its product candidates. Failure of those third parties to perform satisfactorily or to produce sufficient quantities of its product candidate, could delay, prevent or impair the completion of such trials or the development or commercialization of such product.
- If the Company decides to pursue collaborations with third parties for the development or commercialization of its product candidates, but is not able to establish collaborations on commercially reasonable terms, it may have to alter its development and commercialization plans. If it does enter into collaborations that are not successful, it may not be able to capitalize on the market potential of these product candidates.
- The Company's business operations and current and future relationships with healthcare professionals, clinical investigators, consultants, patient organizations, customers, CROs and third party payors in connection with its current and future business activities may be subject to various 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 the Company to various sanctions, penalties, contractual damages or diminished profits and future earnings.
- The Company will need substantial additional funding in the future. If it is unable to raise capital when needed, or on acceptable terms, it may be forced to delay, reduce and/or eliminate one or more of its research and development programs or its future commercialization efforts.
- A number of internal and external factors could impact the stock price and trading volume of the Company’s stock, and investors could lose all or part of their investment.
- The Company has been incurring increased costs as a result of operating as a public company, and its management is required to devote substantial time to compliance initiatives and corporate governance practices. Additionally, if the Company fails to maintain proper and effective internal control over financial reporting, its ability to produce accurate financial statements on a timely basis could be impaired.
- The Company disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Risks Related to the Company's Business

The Company is a clinical stage biopharmaceutical company with limited operating history. It has incurred significant losses and negative cash flows from operations since its formation and will continue to incur losses for the foreseeable future. Company has no products approved for commercial sale, which may make it difficult for investors to evaluate its current business and predict its future success and viability.

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

The Company does not have any products approved for sale, has not generated any revenue and has incurred net losses in each reporting period since its formation. The Company has funded its operations primarily from the sale and issuance of its securities. Additionally, the net losses the Company incurs may fluctuate significantly from quarter to quarter such that a period-to-period comparison of its results of operations may not be a good indicator of the Company's future performance. The size of the Company future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenue.

The Company expects to continue incurring significant expenses and increasing operating losses for the foreseeable future. The Company expects that its expenses will increase substantially if and as it:

- initiates additional preclinical, clinical and other studies for its product candidates or expands or modifies existing studies or currently planned studies;
- changes or adds additional manufacturers or suppliers, some of which may require additional permits or other governmental approvals;
- creates additional infrastructure to support its operations as a public company and its product development and planned future commercialization efforts;
- seeks marketing approvals and reimbursement for its product candidates;
- establishes a sales, marketing, and distribution infrastructure to commercialize any products for which it may obtain marketing approval;
- seeks to identify and develop additional product candidates;
- acquires or in-licenses other product candidates and technologies;
- makes milestone or other payments in connection with the development or approval of its product candidates;
- maintains, protects, and expands its intellectual property portfolio; and
- experiences any delays or encounters issues with any of the above.

The Company's prior losses and expected future losses have had and will continue to have an adverse effect on working capital and ability to achieve and maintain profitability.

The Company is highly dependent on the success of its lead product candidate OC-01 (varenicline) nasal spray for the treatment of dry eye disease. If it is unable to successfully obtain the marketing approvals necessary to commercialize OC-01 (varenicline) nasal spray or experiences significant delays in doing so, or if after obtaining marketing approvals, the Company fails to successfully commercialize this product candidate, its business will be materially harmed.

The Company has devoted a significant portion of its financial resources and business efforts to the development of OC-01 (varenicline) nasal spray for the treatment of dry eye disease. Although it is also developing OC-01 (varenicline) nasal spray for other indications and is exploring other potential products, the Company does not anticipate receiving marketing approvals for any product candidates other than OC-01 (varenicline) nasal spray in the next several years. The Company's ability to generate revenues from product sales will depend on its obtaining marketing approval for and commercializing OC-01 (varenicline) nasal spray , and it cannot accurately predict when or if OC-01 (varenicline) nasal spray will receive marketing approval for dry eye disease or a secondary indication. Because the Company has focused its resources and efforts on developing OC-01 (varenicline) nasal spray for dry eye disease, it has 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 commercial potential, and its resource allocation decisions may cause the Company to fail to capitalize on viable product candidates and profitable market opportunities. If the Company fails to successfully develop OC-01 (varenicline) nasal spray for dry eye disease, it may not be able to identify, assess and develop OC-01 (varenicline) nasal spray for other indications or other product candidates on a timely basis, which could materially affect Company's business, financial condition, results of operations and growth prospects.

The Company's business depends entirely on the successful development and commercialization of OC-01 (varenicline) nasal spray and other future product candidates. It currently generates no revenues from sales of any products and may never generate revenue or be profitable.

The Company has no products approved for commercial sale and does not anticipate generating any revenue until either OC-01(varenicline) nasal spray or another product candidate receives the regulatory and marketing approvals necessary for commercialization. Even though the Company has submitted an NDA for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease, it cannot be certain that OC-01 (varenicline) nasal spray will receive regulatory approval, or be successfully commercialized even if the Company receives regulatory approval. The Company's ability to generate revenue and achieve profitability depends significantly on its ability, or any future collaborator's ability, to achieve a number of objectives, including:

- successful and timely completion of preclinical and clinical development of its product candidates, including OC-01 (varenicline) nasal spray and other future product candidates;
- establishing and maintaining relationships with key scientists, CROs and clinical sites for the clinical development, both in the United States and internationally, of its product candidates, including OC-01 (varenicline) nasal spray and other future product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which the Company successfully completes clinical development;
- complying with 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 the Company develops, 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 its product candidates;
- commercial acceptance of the Company's product candidates by patients, the medical community and third party payors;
- identifying, assessing and developing new product candidates;
- protecting Company's rights in its intellectual property portfolio, including, obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally, and;
- 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 its existing or acquired product candidates;
- obtaining coverage and adequate reimbursement by government and third party payors for product candidates that the Company develops;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

The Company may never be successful in achieving its objectives and, even if it does, 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 it does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. The Company's failure to become and remain profitable would decrease its value and could impair its ability to maintain or further its research and development efforts, raise necessary additional capital, grow business, retain key employees and continue its operations.

The Company's lead product candidate OC-01 (varenicline) nasal spray is based on an API that is already on the market, which exposes the Company 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 ®, indicated as 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, the Company anticipates 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 the Company product candidate, or reporting thereof could prevent or inhibit the commercialization of OC-01 (varenicline) nasal spray and seriously harm Company's business. Furthermore, if manufacturer demand for varenicline increases in the future, particularly as a result of generic forms of varenicline becoming available, the Company may not be able to continue to obtain varenicline on commercially reasonable terms, which would seriously harm Company's business.

OC-01 (varenicline) nasal spray uses a novel and unproven therapeutic approach and mechanism of action to treat dry eye disease and there is no guarantee that OC-01 (varenicline) nasal spray or any other product candidates will be approved by the FDA.

The Company is developing OC-01 (varenicline) nasal spray as a preservative-free, aqueous nasal spray that will stimulate the lacrimal functional unit (LFU) to produce natural tear film. To the Company's knowledge, OC-01 (varenicline) nasal spray represents the first pharmacological treatment approach for dry eye disease that is aimed at stimulating the LFU. Other than with respect to data from the 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. Moreover, even though preclinical studies and clinical trials of OC-01 (varenicline) nasal spray have supported the submission of a 505(b)(2) NDA for the treatment of dry eye disease, the Company may not succeed in demonstrating safety and efficacy of OC-01 (varenicline) nasal spray for other indications, including NK, which is the disease being studied in OLYMPIA, the Company's upcoming Phase 2 clinical trial. Advancing OC-01 (varenicline) nasal spray as a novel product creates significant challenges for the Company, including:

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

The Company cannot guarantee that OC-01 (varenicline) nasal spray or any of its 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 OC-01 (varenicline) nasal spray met the primary endpoint in ONSET-2 in both the 1.2 mg/ml and 0.6 mg/ml dose groups, OC-01 (varenicline) nasal spray did not meet the secondary endpoint for patient-reported symptoms of eye dryness in a Controlled Adverse Environment (CAE®) and other secondary endpoints in either dose group. Following completion of ONSET-2, the Company conducted additional analyses on a post-hoc basis of the data from its ONSET-2 study to support its NDA submission. The Company may also conduct additional post-hoc analyses on the results of clinical trials in the future. Post-hoc analyses performed after unmasking trial results can result in the introduction of bias, may not be predictive of success in any future clinical trials and are given less weight by regulatory authorities than pre-specified analyses. Additionally, the Company cannot guarantee that the safety profile of OC-01 (varenicline) nasal spray in healthy volunteers and patients with dry eye disease 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, the Company's clinical trial outcomes. In addition, participants treated with OC-01 (varenicline) nasal spray may also be treated with other investigational drugs, prescription drugs or even over-the-counter treatments following the treatment period of the Company's OC-01 studies, any of which can cause side effects or adverse events that are unrelated to the Company's 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 (varenicline) nasal spray's safety profile.

The Company may experience delays with respect to FDA's review of the OC-01 (varenicline) nasal spray NDA as the pandemic-related workload at the agency may require diversion of personnel away from review of products that are not used to treat or prevent SARS-CoV-2 and travel restrictions may delay or prevent the inspection of clinical sites or manufacturing operations that are necessary to support approval decisions.

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 the Company's clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities, and the Company 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. The Company cannot give any assurance that any of its 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 the Company's product candidates, the Company must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that its 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 the Company's product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of the Company's 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.

The Company may also experience issues in implementing its clinical trials that would delay or prevent it from satisfying the applicable requirements of the FDA and other regulatory authorities, including:

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

The Company may be unable to design and execute clinical trials that support marketing approval. It cannot be certain that any of its future clinical trials will be successful. For example, use of OC-01 (varenicline) nasal spray 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 (varenicline) nasal spray in demonstrating efficacy in future clinical trials, such as the OLYMPIA trial in NK. Additionally, any safety concerns observed in any one of the Company's clinical trials in its targeted indications could limit the prospects for regulatory approval of its product candidates in NK and potentially other indications, which could materially affect the Company's business, financial condition, results of operations and growth prospects.

In addition, even if such clinical trials are successfully completed, the Company cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as the Company does, and more trials could be required before it submits its 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, the Company may be required to expend significant resources, which may not be available to it, to conduct additional trials in support of potential approval of its product candidates. Even if regulatory approval is secured for any of the Company's product candidates, the terms of such approval may limit the scope and use of its product candidate, which may also limit its commercial potential.

If the Company experiences delays or difficulties in the enrollment of subjects in clinical trials, its receipt of necessary regulatory approvals could be delayed or prevented.

The Company may not be able to initiate or continue clinical trials for its product candidates if it is 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 the Company experiences relating to the initiation or completion of patient visits in clinical trials, including as impacted by the SARS-CoV-2 virus, could delay regulatory approval for its product candidates.

Patient enrollment may be affected if the Company’s competitors have ongoing clinical trials for product candidates that are under development for the same indications as its product candidates, and subjects who would otherwise be eligible for clinical trials instead enroll in clinical trials of the Company’s competitors’ product candidates. Patient enrollment for any of the Company’s 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;
- ECPs' and participants' perceived risks and benefits of the product candidate under study in relation to

other available therapies, including any new products that may be approved for the indications the Company is 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;
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion; and
- disruptions or difficulties, or other restrictions, in initiating, enrolling, conducting or completing trials due to the SARS-CoV-2 virus outbreak.

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

The Company may also face challenges in collecting data from follow up visits related to its enrolled clinical trials. For example, due to the SARS-CoV-2 virus outbreak, select clinical trial sites in the Company's ONSET-2 clinical trial were closed and subjects were unable to attend visits per the trial protocol, which reduced the amount of data the Company was able to collect for subjects at these affected centers with respect to primary and secondary endpoints. The Company believes that this inability to collect data had an adverse impact on the statistical powering of certain of its secondary endpoints in ONSET-2 and may impact its future clinical trial results.

The Company's 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 the Company obtains approval for any of its 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 Company's ability to market the product.

Adverse events or other undesirable side effects caused by or associated with treatment by the Company's product candidates could cause it 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 the Company tests its 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-2, ONSET-1, ZEN and MYSTIC were non-ocular in nature, which were sneezing and coughing. If approved, the Company expects that OC-01 (varenicline) nasal spray will be used chronically over a prolonged period of time. However, the Company has no clinical safety data on patients treated with OC-01 (varenicline) nasal spray 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. The Company's understanding of the relationship between its product candidates and these adverse events may change as it gathers more information, and additional unexpected adverse events may occur. If additional clinical experience indicates that OC-01 (varenicline) nasal spray 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 the Company's business, growth prospects, operating results and financial condition.

Additionally, if one or more of the Company's product candidates receives marketing approval, and it 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;
- it may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;

- it 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;
- it could be sued and held liable for harm caused to patients; and
- its reputation may suffer.

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

Interim, topline and preliminary data from the Company's clinical trials that it announces or publishes from time to time may change as more patient data become available and is subject to audit and verification procedures that could result in material changes in the final data.

From time to time, the Company may publicly disclose preliminary, interim or topline data from its 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. The Company also makes assumptions, estimations, calculations and conclusions as part of its analyses of data, and it may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that the Company reports 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 the Company previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, the Company may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that the Company 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 the Company's business, financial condition, results of operations and growth prospects. Further, additional disclosure of interim data by the Company or by its competitors in the future could result in volatility in the price of the Company common stock. Further, others, including regulatory agencies, may not accept or agree with the Company 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 the Company in general. In addition, the information the Company chooses to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Investors may not agree with what it determines is the material or otherwise appropriate information to include in its disclosure, and any information it determines not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or the Company's business. If the preliminary or topline data that the Company reports differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, its ability to obtain approval for, and commercialize the Company product candidates may be harmed, which could materially affect its business, financial condition, results of operations and growth prospects.

The Company's success is highly dependent on its ability to attract and retain highly skilled executive officers and employees.

To succeed, the Company must recruit, retain, manage and motivate qualified executives as it builds out the management team, and the Company faces significant competition for experienced personnel. The Company is highly dependent on the principal members of its management and needs to continue to add executives with operational and commercialization experience as it plans for commercialization of its product candidates and builds out a leadership team that can manage its operations as a public company. If the Company does not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect its ability to execute the Company's business plan and harm its operating results. In particular, the loss of one or more of its executive officers could be detrimental if no suitable replacement is recruited in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, the Company may be unable to continue to attract and retain qualified personnel necessary for the future success of its business. The Company could in the future have difficulty attracting experienced personnel and may be required to expend significant financial resources in its employee recruitment and retention efforts.

Many of the other biotechnology companies that the Company competes against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry. 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 the Company has to offer. If the Company is unable to continue to attract and retain high-quality personnel,

the rate and success at which it can discover, develop and commercialize its product candidates will be limited and the potential for successfully growing its business will be harmed.

If the Company engages in acquisitions, in-licensing or strategic partnerships, this may increase its capital requirements, dilute stockholders, cause it to incur debt or assume contingent liabilities and subject the Company to other risks.

The Company 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 equity securities which would result in dilution to the Company's stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of management's attention from the Company's 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 its 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
- the Company's inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet its objectives or even to offset the associated transaction and maintenance costs.

The Company's information technology systems, or those used by the Company's third party research institution collaborators, CROs, contractors or consultants, may fail or suffer other breakdowns, cyber-attacks or information security breaches that could compromise such systems and data, expose the Company to liability, affect its reputation and otherwise harm its business.

The Company is increasingly dependent upon information technology systems, infrastructure, and data to operate its business, particularly during the SARS-CoV-2 virus pandemic. The Company also relies on third party vendors and their information technology systems. Despite the implementation of security measures, the Company's computer systems and those of its CROs, third-party vendors, contractors and consultants may be vulnerable to compromise from traditional computer hackers; malicious code (such as computer viruses or worms); employee error, theft or misuse; denial-of-service attacks; cyber-attacks by sophisticated nation-state and nation-state supported actors; or other system disruptions. There can be no assurance that the Company, its collaborators, CROs, third-party vendors, contractors and consultants 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.

As the cyber-threat landscape evolves, these attacks will grow in frequency, sophistication and intensity and will become increasingly difficult to detect. Cyber-threats may be generic, or they may be targeted against the Company's information systems. The Company and its third-party vendors may not be able to anticipate all types of security threats, and the Company may not be able to implement effective preventive measures against all such security threats. As a result of the SARS-CoV-2 virus pandemic, the Company may face increased cybersecurity risks due to its reliance on internet technology and the number of its employees that are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

The costs to respond to a security breach and/or to mitigate any identified security vulnerabilities could be significant, the Company's efforts to address these issues may not be successful, and these issues could result in interruptions, delays, negative publicity, loss of customer trust, diminished purchase or use of our products, and other harms to the Company's business and competitive position. Remediation of any potential security breach may involve significant time, resources, and expenses. Any security breach may result in regulatory inquiries, litigation or other investigations, and could negatively impact the Company's financial and operational condition. The Company could be required to fundamentally change its business activities and practices in response to a security breach and our systems or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation.

If a breakdown, cyber-attack or other information security breach were to occur, it could result in a material disruption of the Company's development programs and business operations, whether due to a loss of trade secrets or other proprietary information. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in the Company's regulatory approval efforts and significantly increase its costs to recover or reproduce the data. Likewise, the Company relies on its third-party research institution collaborators for research and development of its product candidates and

other third parties for the manufacture of its product candidates and to conduct clinical trials, and similar events relating to their information systems could also have a material adverse effect on the Company's business.

The Company receives, generates and stores significant and increasing volumes of sensitive, confidential and/or proprietary information, including personal data (such as health information), research and development information, and commercial information (such as business and financial information). While the Company has security measures in place that are designed to protect such information and prevent security breaches, there can be no assurance that the Company's security measures or those of the Company's third-party service providers that store or otherwise process the Company's information on our behalf will be effective.

The Company is required to comply with laws, rules, regulations and other obligations that require it to maintain the security of personal information. It may have contractual and other legal obligations to notify relevant stakeholders of security breaches. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving personal information. For example. in the United States, notice of breaches of protected health information as defined under the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA) may need to be disclosed to affected individuals, the U.S. Secretary of the Department of Health and Human Services (HHS), and others.

A security breach may cause the Company to breach its contracts. The Company's agreements with relevant stakeholders such as collaborators may require the Company to use legally required, industry-standard or reasonable measures to safeguard personal information. A security breach could lead to claims by relevant stakeholders that the Company has failed to comply with such contractual obligations. In addition, any non-compliance with the Company's data privacy obligations in its contracts or the Company's inability to flow down such obligations from relevant stakeholders to the Company's vendors may cause the Company to breach its contracts. As a result, the Company could be subject to legal action or the relevant stakeholders could end their relationships with it. There can be no assurance that the limitations of liability in the Company's contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages.

The Company does not maintain standalone cyber-security insurance and has limited insurance coverage in the event of any breach or disruption of its or its collaborators', CROs', or vendors' systems, including any unauthorized access or loss of any personal data that the Company may collect, store or otherwise process. The costs related to significant security breaches, disruptions or data breaches could be material and exceed the limits of any insurance coverage the Company may have. In addition, the Company cannot be sure that its existing insurance coverage will continue to be available on acceptable terms or that its insurers will not deny coverage as to any future claim. To the extent any disruption, data breach or security breach were to result in a loss of, or damage to, the Company's data or systems, or inappropriate disclosure of confidential or proprietary information, including personal data, the Company could incur liability and the further development and commercialization of its product candidates could be delayed and its 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 the Company.

The Company is subject to stringent and evolving laws, regulations, rules, contractual obligations, and policies related to data privacy and security, and its actual or perceived failure to comply with such obligations could harm its business.

The Company's business is subject to stringent and evolving U.S. and foreign laws, rules, and regulations, and contractual obligations relating to data privacy and security, including the use, processing, and cross-border transfer of personal data. Data privacy has become a significant issue in the United States, countries in the European Union, or EU, and in many other countries in which it may operate. The regulatory frameworks for privacy issues are evolving and may result in ever-increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions, including monetary penalties and personal data processing penalties that could require us to change our business practices. Interpretation of these frameworks is likely to remain uncertain and potentially inconsistent for the foreseeable future. This evolution may create uncertainty in our business, affect our or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer, use or share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Despite the Company's efforts to bring practices into compliance with these obligations, it may not be successful in its efforts to achieve compliance either due to internal or external factors such as resource allocation limitations or a lack of vendor cooperation. Noncompliance could result in proceedings against the Company by governmental and regulatory entities, collaborators, data subjects or others.

In the U.S., these include rules and regulations promulgated under the authority of the Federal Trade Commission and the following laws and regulations: the Electronic Communications Privacy Act, the Computer Fraud and Abuse Act, the California Consumer Privacy Act of 2018, or the CCPA, and other state and federal laws relating to data privacy and security. For example, the CCPA, which became effective on January 1, 2020, establishes a privacy framework for covered businesses, including an expansive definition of personal information and data privacy rights for California residents. The CCPA, among other things, requires covered businesses to provide disclosures to California residents and afford such individuals data protection rights, including the ability to opt-out of the sale of personal information. The CCPA provides a private right of action and statutory damages for violations, including for data breaches. Although the CCPA exempts certain data regarding clinical trials,

the CCPA, to the extent applicable to the Company's business and operations, may increase the Company's compliance costs and potential liability with respect to other personal information the Company maintains about California residents. In addition, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, that goes into effect on January 1, 2023. It is expected that the CPRA would, among other things, give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. These laws reflect our Company's vulnerability to the evolving regulatory environment related to personal information.

Internationally, the Company's operations may be subject to increased scrutiny or attention from foreign data protection authorities. The Company's clinical trial programs and research collaborations outside the United States may implicate foreign data protection laws, including in Europe. Many jurisdictions have established, or are in the process of establishing, privacy and data security legal frameworks with which we, the Company's collaborators, service providers, including the Company's CROs, and contractors must comply. For example, European data protection laws, including, without limitation, the EU's General Data Protection Regulation, or GDPR, impose stringent data protection requirements for processing the personally identifiable information of individuals residing in the European Economic Area, Switzerland, and United Kingdom. For example, these laws impose robust disclosure requirements to individuals and a strengthened individual data rights regime, strict 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 the Company contracts with third-party processors in connection with the processing of the personal data. The GDPR increases the Company's obligations with respect to clinical trials conducted in the EU by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial participants and investigators. The GDPR provides for fines for noncompliance of up to €20 million or four percent of worldwide annual revenues, whichever is greater. In addition, the GDPR authorizes penalties for non-compliance and civil litigation claims.

The GDPR applies extraterritorially, and the Company may be subject to the GDPR because of its 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 the Company processes, and it 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 the Company's development activities, and adversely affect its business, financial condition, results of operations and growth prospects.

European data protection laws, including the GDPR, generally restrict the transfer of personal information from Europe, including the European Economic Area, United Kingdom, and Switzerland (collectively, Europe) to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. One of the primary safeguards used for transfers of personal data from Europe to the United States, namely, the Privacy Shield administered by the U.S. Department of Commerce, was invalidated by a decision of Court of Justice of the European Union (CJEU). Subsequently, the Swiss Federal Data Protection and Information Commissioner also opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of data from Switzerland to the U.S. The CJEU also cast doubt on our ability to use one of the primary alternatives to the Privacy Shield, namely the European Commission's Standard Contractual Clauses, to transfer lawfully personal data from Europe to the United States and most other countries. Further, the European Commission recently proposed updates to the Standard Contractual Clauses. At present, there are few if any viable alternatives to the Standard Contractual Clauses and, therefore, there is uncertainty regarding how to ensure that transfers of personal information from Europe to the U.S. and other countries comply with European data protection laws. As such, any transfers by the Company, or the Company's third party vendors, of personal data from Europe may not comply with European data protection laws; may increase the Company's exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions, and may restrict our clinical trial activities in Europe, limit our ability to collaborate with CROs, service providers and other companies subject to European data protection laws. Loss of the Company's ability to transfer personal data from Europe may also require us to increase the Company's data processing capabilities in those jurisdictions at significant expense.

Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, created uncertainty with regard to data protection regulation in the United Kingdom. Following December 31, 2020, the GDPR's data protection obligations continue to apply to the United Kingdom in substantially unvaried form under the so called "UK GDPR" or more explicitly, the GDPR continues to form part of the laws in the United Kingdom by virtue of section 3 of the European Union (Withdrawal) Act 2018, as amended (including by the various Data Protection, Privacy and Electronic Communications (EU Exit) Regulations), which potentially exposes us to two parallel data protection regimes, each of which authorizes fines and the potential for divergent enforcement actions. In addition, it is still unclear whether the transfer of personal data from the EU to the United Kingdom will in the future continue to remain lawful under the GDPR. For example, pursuant to a post-Brexit agreement between the United Kingdom and the EU, the European Commission will continue to treat the United Kingdom as if it remained a member state of the EU in relation to transfers of personal data from the EEA to the United Kingdom, meaning such transfers may be made without a need for additional safeguards, for four months from January 1, 2021, with a potential additional two month extension. This

“transition” period, however, will end if and when the European Commission adopts an adequacy decision in respect of the United Kingdom or the United Kingdom amends certain UK data protection laws, or relevant aspects thereof, without the EU’s consent (unless those amendments are made simply to align those UK data protection laws with the EU’s data protection regime). If the European Commission does not adopt an adequacy decision with regard to personal data transfers to the United Kingdom before the expiration of the transition period, from that point onwards, the United Kingdom will be a “third country” under the GDPR and such transfers will need to be made subject to GDPR-compliant safeguards (for example, the Standard Contractual Clauses).

Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, and strict requirements and limitations for processing personal information, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil enacted the General Data Protection Law, New Zealand enacted the New Zealand Privacy Act, China released its draft Personal Information Protection Law, and Canada introduced the Digital Charter Implementation Act. As with the GDPR, these laws are broad and may increase our compliance burdens, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how the Company collects, uses, discloses, retains, and processes personal information about them.

The Company publishes privacy policies and other documentation regarding the Company’s collection, processing, use and disclosure of personal information. Although the Company endeavors to comply with the Company’s published policies and other documentation, the Company may at times fail to do so or may be perceived to have failed to do so. Moreover, despite the Company’s efforts, the Company may not be successful in achieving compliance if the Company’s employees or third-party vendors fail to comply with the Company’s published policies and documentation. Such failures can subject the Company to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of the Company’s actual practices. Moreover, subjects about whom the Company or the Company’s partners obtain information, as well as the providers who share this information with us, may contractually limit the Company’s ability to use and disclose the information. Claims that the Company has violated individuals’ privacy rights or failed to comply with data protection laws or applicable privacy notices even if the Company is not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm the Company’s business.

Changes in U.S. tax law may materially adversely affect the Company's financial condition, results of operations and cash flows.

On March 27, 2020, the CARES Act was signed into law to address the SARS-CoV-2 virus pandemic crisis. The CARES Act is an approximately $2 trillion emergency economic stimulus package that includes numerous U.S. federal income tax provisions, including the modification of: (i) net operating loss rules, (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163(j) of the Internal Revenue Code of 1986, as amended (the Code).). On Dec. 27, 2020, President Trump signed the Consolidated Appropriations Act, 2021 (H.R. 133), an appropriations and stimulus package that includes many U.S. federal income tax provisions generally favorable to taxpayers such as (i) retroactive changes to and extensions of items contained in The CARES Act, and (ii) extensions of dozens of expiring tax provisions including the employer tax credit for paid family and medical leave.

The Tax Act also significantly changed the U.S. federal income taxation of U.S. corporations. The Tax Act remains unclear in many respects and has been, and may continue to be, the subject of amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service (the IRS), which have lessened or increased certain adverse impacts of the Tax Act and may continue to do so in the future. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. The Company continues to work with its tax advisors to determine the full impact the Tax Act, the CARES Act, and H.R. 133 will have. The Company's investors should consult with their legal and tax advisors with respect to both the Tax Act and the CARES Act and the potential tax consequences of investing in the Company's common stock.

The Company's ability to use its net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.

The Company's net operating loss carryforwards (NOLs) and certain other tax attributes 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. The Company's 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. As of December 31, 2020, the Company had a U.S. federal NOL carryforward balance of $120.6 million, $4.5 million of which will expire beginning in the year 2035, if unutilized, and $116.1 million of which will carry forward indefinitely. As of December 31, 2020, the Company had a state NOL carryforward balance of $123.9 million, which will expire beginning in the year 2035, if unutilized.

Under the Tax Act, federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely. Under the CARES Act, NOLs arising in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss. Due to the Company's cumulative losses through December 31, 2020, it does not anticipate that such provision of the CARES Act will be relevant to it. The deductibility of federal NOLs, particularly for tax years beginning after December 31, 2020, may be limited. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

In addition, the Company's NOLs and tax credit carryforwards are subject to review and possible adjustment by the IRS and state tax authorities. Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the Company's 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. The Company determined that no significant limitation would be placed on the utilization of its net operating loss and tax credit carryforwards due to prior ownership changes. The Company may, however, experience ownership changes in the future as a result of equity offerings or subsequent shifts in its stock ownership, some of which are outside its control. If the Company's ability to utilize those NOLs and tax credit carryforwards becomes limited by an "ownership change" as described above, it may not be able to utilize a material portion of its NOLs and certain other tax attributes, which could have a material adverse effect on its cash flows and results of operations.

Risks Related to Development and Commercialization of the Company's 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 the Company's product candidates, particularly OC-01 (varenicline) nasal spray, are prolonged or delayed, the Company may be unable to obtain required regulatory approvals, and therefore be unable to commercialize its product candidates on a timely basis or at all.

Before obtaining marketing approval from regulatory authorities for the sale of its product candidates, the Company must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. To date, the Company has focused substantially all of its efforts and financial resources on identifying, acquiring, and developing its product candidates, including conducting preclinical studies and clinical trials. Clinical testing is expensive and can take many years to complete, and the Company cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. The Company's inability to successfully complete preclinical and clinical development could result in additional costs to it and negatively impact its ability to generate revenue. The Company's future success is dependent on its ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates. The Company currently does not generate any revenues from sales of any products, and it may never be able to develop or commercialize a marketable product.

Each of the Company's product candidates may 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 the Company generates any revenues from product sales. The Company is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA or comparable foreign regulatory authorities, and it may never receive such regulatory approval for any of its product candidates. The Company may experience delays in its ongoing clinical trials and it does 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.

The Company may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent its ability to receive marketing approval or commercialize OC-01 (varenicline) nasal spray and any other product candidates that it may develop, including:

- the Company 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
- the Company may fail to obtain sufficient enrollment in its clinical trials or participants may fail to complete its clinical trials;
- clinical trials of its product candidates may produce negative or inconclusive results, and it may decide, or regulators may require the Company, to conduct additional clinical trials or abandon product development programs;
- the Company may decide, or regulators or institutional review boards may require it, 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 the Company to perform additional or unanticipated clinical trials to obtain approval or it may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving its product candidates, or such requirements may not be as it anticipates;
- the cost of clinical trials of its product candidates may be greater than it anticipates, and the Company may need to delay or suspend one or more trials until it completes additional financing transactions or otherwise receive adequate funding;
- the supply or quality of its product candidates or other materials necessary to conduct clinical trials of its product candidates may be insufficient or inadequate or may be delayed;
- the Company's product candidates may have undesirable side effects or other unexpected characteristics, causing it or its investigators, regulators or institutional review boards to suspend or terminate trials;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- the Company may experience delays due to the SARS-CoV-2 virus pandemic, including with respect to the receipt of product candidates or other materials, submission of NDAs, filing of Investigational New Drug Application, or INDs and starting any clinical trials for other indications or programs;
- the Company may experience delays with respect to FDA's review of the OC-01 (varenicline) nasal spray NDA as the pandemic-related workload at the agency may require diversion of personnel away from review of non-pandemic products and travel restrictions may delay or prevent the inspection of clinical sites or manufacturing operations that are necessary to support approval
decisions; and
- the Company may experience manufacturing delays due to the SARS-CoV-2 virus pandemic in its supply chain caused by a shortage of raw materials, a lack of employees on site at its suppliers due to illness, or a lack of productivity at its suppliers due to local or national government quarantine restrictions on coming to the workplace.

For example, due to the SARS-CoV-2 virus pandemic, the Company experienced an impact at select clinical trial sites during the month of March 2020 where ophthalmology practices were closed or subjects were unable to attend visits or where clinical trial sites did not feel comfortable putting their staff or subjects into a CAE®, which limited the Company's ability to assess the related secondary endpoint in its ONSET-2 study for those subjects. The Company does not know whether any of its preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If the Company experiences delays in the completion of, or termination of, any clinical trial of its product candidates, or is unable to achieve clinical endpoints due to unforeseen events, such as the SARS-CoV-2 virus pandemic, the commercial prospects of its product candidates will be harmed, and its ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing its clinical trials will increase the Company's costs, slow down its product candidate development and approval process and jeopardize its ability to commence product sales and generate revenues. Significant clinical trial delays could also allow the Company's competitors to bring products to market before it does or shorten any periods during which the Company has the exclusive right to commercialize its product candidates and impair its ability to commercialize its product candidates and may harm its business and results of operations.

OC-01 (varenicline) nasal spray and the Company's 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, the Company's third party manufacturer has only manufactured OC-01 (varenicline) nasal spray in limited quantities in batch sizes appropriate for the Company's clinical trials and registration batches to support the NDA submission, for which batch sizes are a fraction of the size the Company expects 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 the Company plans to manufacture commercial scale batches of OC-01 (varenicline) 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 the Company's manufacturer will be successful in establishing a larger-scale commercial manufacturing process for

OC-01 (varenicline) nasal spray that achieves its objectives for manufacturing capacity and cost of goods, in a timely manner or at all. In addition, there is no assurance that the Company manufacturers will be able to manufacture OC-01 (varenicline) nasal spray 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 (varenicline) nasal spray or to meet potential future demand. If the 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, the Company's commercialization efforts would be impaired, including impacting the launch of OC-01 (varenicline) nasal spray or inventory levels, which could materially affect Company's business, financial condition, results of operations and growth prospects.

The commercial success of the Company's products depends on the availability and sufficiency of third party payor coverage and reimbursement.

Patients in the United States and elsewhere generally rely on third party payors to reimburse part or all of the costs associated with their prescription drugs. Accordingly, market acceptance of the Company's products is dependent on the extent to which third party coverage and reimbursement is available from third party payors, including government health administration authorities (including in connection with government healthcare programs, such as Medicare and Medicaid), private healthcare insurers and other healthcare funding organizations.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which the Company may obtain regulatory approval. Coverage decisions may not favor new products when more established or lower cost therapeutic alternatives are already available. Even if the Company obtains coverage for a given product, the associated reimbursement rate may not be adequate to cover its costs, including research, development, intellectual property, manufacture, sale and distribution expenses, or may require copayments that patients find unacceptably high. Patients are unlikely to use the Company's products unless reimbursement is adequate to cover all or a significant portion of the cost of its products.

Coverage and reimbursement policies for products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for products among third party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly which will require the Company to provide scientific and clinical support for the use of its products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained.

In addition, the Company expects that the increased emphasis on managed care and cost containment measures in the United States by third party payors and government authorities to continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which the Company receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If the Company is unable to obtain and maintain sufficient third party coverage and adequate reimbursement for its products, the commercial success of these products may be greatly hindered and the Company's financial condition and results of operations may be materially and adversely affected.

The Company's business, operations and clinical development timelines and plans could be adversely affected by the effects of health epidemics, including the SARS-CoV-2 virus pandemic.

The Company's business, operations and clinical development timelines and plans could be adversely affected by health epidemics in regions where it has concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third party contractors upon which it relies. In March 2020, the World Health Organization declared the outbreak of a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19, to be a global pandemic. The pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended and demand for certain goods and services has fallen.

The President of the United States declared the SARS-CoV-2 virus pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response and powers under the Defense Production Act, the legislation that facilitates the production of goods and services necessary for national security and for other purposes. In addition, in response to the SARS-CoV-2 virus pandemic, many state, local and foreign governments have put in place, and others in the future may put in place, quarantines, executive orders, shelter-in-place orders and similar government orders and restrictions in order to control the spread of the disease. Such orders or restrictions, and the perception that such orders or restrictions could occur, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects that could negatively impact productivity and disrupt the Company's business and operations. For example, the Company's headquarters and certain of its trial sites are located in New Jersey, and in March 2020, the Governor of New Jersey announced that all businesses, excluding essential services, must decrease their in-office workforce by 100%. While some of these governmental restrictions have been lifted, the timing and extent to which

such orders and restrictions will be removed remains uncertain. The Company has implemented a work-from-home policy for all employees, and it continues evaluating the situation as more information about the virus becomes available. Moreover, the Company's clinical development timelines and plans could be affected by the SARS-CoV-2 virus pandemic. Site initiation and patient enrollment could be delayed or suspended due to prioritization of hospital resources toward the SARS-CoV-2 virus pandemic. In addition, some patients may not be able to comply with clinical trial protocols and the ability to conduct follow up visits with treated patients may be limited if quarantines impede patient movement or interrupt healthcare services. For example, due to the SARS-CoV-2 virus pandemic, select clinical trial sites in ONSET-2 clinical trial were closed and subjects were unable to attend visits per the trial protocol, which reduced the number of patients for which the Company collected data on with respect to its primary and secondary endpoints. In addition, due to the SARS-CoV-2 virus pandemic, a number of clinical trial sites for ONSET-2 did not feel comfortable putting their staff or subjects into the required CAE®, which limited the Company's ability to assess the related secondary endpoint for those subjects, which might have contributed to not achieving certain secondary endpoints in ONSET-2. The Company cannot assure that the inability to collect such data would not also have an adverse impact on its future clinical trial results. Similarly, the Company's ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to SARS-CoV-2 virus pandemic could be adversely impacted.

The continued spread of the SARS-CoV-2 virus pandemic could severely impact the Company's business, preclinical studies, and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate planned clinical trials;
- delays or difficulties in enrolling and retaining patients in clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the SARS-CoV-2 virus pandemic which may require the Company to change ways in which clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that patient recruitment in the Company’s clinical trials will be impacted due to pandemic-related lockdowns or stay-at-home advisories;
- risk that participants enrolled in the Company's clinical trials will acquire SARS-CoV-2 virus while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA to accept data from clinical trials in affected geographies;
- interruption or delays to the Company's sourced discovery and clinical activities;
- increased cybersecurity risks due to the Company's reliance on internet technology and the number of its employees that are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities; and
- disruption or constraints at manufacturers, which could result in product manufacturing delays.

It is highly uncertain and difficult to predict the full extent of the economic impact brought by and the duration of SARS-CoV-2 virus pandemic; the pandemic could still result in significant disruption of global financial markets, reducing the Company's ability to access capital, which could in the future negatively affect its liquidity. In addition, a recession or market correction resulting from the spread of SARS-CoV-2 virus pandemic could materially affect its business and value of Company's common stock.

The global SARS-CoV-2 virus pandemic continues to rapidly evolve, and the Company will continue to monitor the SARS-CoV-2 virus pandemic situation closely. The ultimate impact of the SARS-CoV-2 virus pandemic or a similar health epidemic is highly uncertain and subject to change. The Company does not yet know the full extent of the potential impacts on its business, clinical trials, healthcare systems or the global economy as a whole.

Even if the Company obtains regulatory approval for any of its product candidates, it 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 the Company obtains regulatory approval for OC-01 (varenicline) nasal spray 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 the Company may be subject to penalties if it fails to comply with regulatory requirements or experiences unanticipated problems with such products.

If FDA or a comparable foreign regulatory authority approves any of the Company's product candidates, including OC-01 (varenicline) nasal spray, 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 the Company conducts post-approval, all of which may result in significant expense and limit its ability to successfully commercialize such products. In addition, any regulatory approvals that the Company receives for its 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.

Any later discovery of previously unknown problems with the Company product candidates, including adverse events of unanticipated severity or frequency, or problems with its 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 the Company, 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.

The Company's ongoing regulatory requirements may also change from time to time, potentially harming or making costlier its commercialization efforts. It 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 the Company is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if it's not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained and it may not achieve or sustain profitability, which would adversely affect its business.

The Company faces significant competition, and if its competitors develop and market technologies or products more rapidly than the Company does or that are more effective, safer or less expensive than the product candidates the Company develops, its commercial opportunities will be negatively impacted. The Company's 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. The Company faces competition with respect to OC-01 (varenicline) nasal spray for the treatment of dry eye disease, and will face competition with respect to OC-01 (varenicline) nasal spray for other indications and any other product candidates that it 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 dry eye disease 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 an over-the-counter or generic basis, and the Company product candidates may not demonstrate sufficient additional clinical benefits to ECPs, patients or payors to justify a higher price compared to such products. In many cases, insurers or other third party payors, particularly Medicare, seek to encourage the use of generic products.

The Company's commercial opportunity could be reduced or eliminated if its 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 the

Company's products. The competitors also may obtain FDA or other regulatory approval for their products more rapidly than the Company may obtain approval for its candidates, which could result in competitors establishing a strong market position before the Company is able to enter the market.

In addition, the Company's 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 it is pursuing, and additional products are expected to become available on a generic basis over the coming years.

Many of the companies against which the Company is competing or against which it 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 it does. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of the Company's 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 the Company 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, the Company's programs.

If product liability lawsuits are brought against the Company, it may incur substantial liabilities and may be required to limit commercialization of its products.

The Company's business exposes it 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 the Company's development programs. If 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, the Company's manufacturing processes and facilities or its marketing programs. These investigations could potentially lead to a recall of its 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 the Company's reputation, withdrawal of clinical trial participants, costs to defend the related litigation, a diversion of management’s time and its resources, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize the Company's product candidates and decreased demand for its product candidates, if approved for commercial sale. The Company currently has product liability insurance that it believes is appropriate for its stage of development and may need to obtain higher levels prior to marketing any of its product candidates, if approved. Any insurance it have or may obtain may not provide sufficient coverage against potential liabilities and, if judgments exceed the Company's insurance coverage, could adversely affect its results of operations and business and cause the stock price to decline. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, the Company may be unable to maintain or obtain insurance coverage at a reasonable cost or in sufficient amounts to protect it against losses, including those caused by product liability claims.

A variety of risks associated with marketing the Company's product candidates internationally could materially adversely affect its business.

The Company plans to seek regulatory approval of its product candidates outside of the United States and, accordingly, it expects that it will be subject to additional risks related to operating in foreign countries if it obtains 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;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- 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 the Company's 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 international operations may materially adversely affect the Company's ability to attain or maintain profitable operations.

Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom withdrew from the European Union, commonly referred to as “Brexit”, effective December 31, 2020. On December 24, 2020, the United Kingdom and European Union entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of the Trade and Cooperation Agreement or otherwise, could prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, the Company may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for any product candidates, which could significantly and materially harm our business.

Risks Related to Intellectual Property

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

The Company relies upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to its development programs and product candidates. The Company's success depends in part on its ability to obtain and maintain patent protection in the United States and other countries with respect to OC-01 (varenicline) nasal spray and other product candidates. The Company seeks to protect its proprietary position by filing patent applications in the United States and abroad related to its development programs and product candidates. The patent prosecution process is expensive and time-consuming, and the Company 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 the Company owns may fail to result in issued patents with claims that protect OC-01 (varenicline) nasal spray or other product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to the Company's 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 (varenicline) nasal spray or other product candidates, 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 the Company could deprive it of rights necessary for the successful commercialization of any product candidates that it may develop. Further, if the Company encounters delays in regulatory approvals, the period of time during which it 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 the Company or any of its potential future collaborators will be successful in protecting its product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the U.S. Patent and Trademark office, or 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;
- the Company's competitors, many of whom have substantially greater resources than the Company does 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 the Company's ability to make, use and sell its 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 the Company 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 the Company will fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection. Moreover, if the Company chooses to license

certain patent rights in the future from third parties, it 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 it licenses from those third parties. The Company may also require the cooperation of its 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 the Company's business. The Company cannot be certain that patent prosecution and maintenance activities by any of its 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 the Company to lose rights in any applicable intellectual property that it in-licenses, and as a result its ability to develop and commercialize products or product candidates may be adversely affected and it may be unable to prevent competitors from making, using and selling competing products.

If the patent applications the Company holds or may in-license in the future with respect to its 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 (varenicline) nasal spray or other product candidates, it could dissuade other companies from collaborating with the Company to develop product candidates, and threaten its ability to commercialize OC-01 (varenicline) nasal spray or other product candidates. Any such outcome could have a materially adverse effect on the Company's 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 the Company's 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, the Company cannot know with certainty whether it was the first to make the inventions claimed in its own patents or pending patent applications, or that it 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 the Company patent rights are highly uncertain. The Company's pending and future patent applications may not result in patents being issued which protect its 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 the Company patents or narrow the scope of its patent protection.

Moreover, the Company 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 its patent rights or the patent rights of others. The costs of defending patents or enforcing its 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, the Company's patent rights, allow third parties to commercialize its technology or products and compete directly with the Company, without payment to it, or result in its inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by the Company's patents and patent applications is threatened, it could dissuade companies from collaborating 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 the Company has 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 the Company ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of its 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 the Company's current or future product candidates, it 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, the Company's patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to its own.

Depending upon the timing, duration and specifics of FDA marketing approval of OC-01 (varenicline) nasal spray and other product candidates, one or more of the Company's 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 the Company assessment of whether such extensions are available, and may refuse to grant extensions to its patents, or may grant more limited extensions than the Company requests. The Company 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 the Company requests. If it is unable to extend the expiration date of its existing patents or obtain new patents with longer expiry dates, the Company's competitors may be able to take advantage of its investment in development and clinical trials by referencing its clinical and preclinical data to obtain approval of competing products following its patent expiration and launch their product earlier than might otherwise be the case.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and the Company's 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 the Company's 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 the Company or any of its licensors fail to maintain the patents and patent applications covering OC-01 (varenicline) nasal spray, or other product candidates, the Company's competitors may be able to enter the market, which would have an adverse effect on its business.

The Company 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 its ability to develop and market its products.

The Company cannot guarantee that any of its 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 it be certain that it has 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 its 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. The Company's interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact its ability to market its products. The Company may incorrectly determine that its 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. The Company's determination of the expiration date of any patent in the United States or abroad that it considers relevant may be incorrect, and its failure to identify and correctly interpret relevant patents may negatively impact its ability to develop and market its products.

Third party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate the Company's patents or other proprietary rights, may delay or prevent the development and commercialization of OC-01 (varenicline) nasal spray and any other product candidates.

The commercial success depends in part on the Company 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 the Company and its collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as the Company gains greater visibility and market exposure as a public company, the risk increases that the Company 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 the Company is 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 the Company's 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 current or future product candidates may infringe.

The Company is aware of two issued U.S. patents owned by Pfizer (U.S. Pat. No.: 7,265,119 (the ‘119) and 6,890,927 (the ‘927) 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 the Company's candidate OC-01 (varenicline) nasal spray. Of the two issued patents, the Company anticipates that both will be in force at the time that it could expect to receive FDA approval of OC-01 (varenicline) nasal spray and on October 18, 2019, the Company entered into a non-exclusive patent license for these patents. However, even with the aforementioned license, the Company cannot provide assurances that third parties won’t allege infringement, which could delay or prevent the development and commercialization of OC-01 (varenicline) nasal spray or other product candidates.

In addition, third parties may obtain patent rights in the future and claim that use of the Company 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 the Company's product candidates, any molecules formed during the manufacturing process, methods of treating certain diseases or conditions that it is pursuing with its product candidates, its formulations including combination therapies, or any final product itself, the holders of any such patents may be able to block its ability to commercialize such product candidate unless the Company 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, the Company may be subject to claims that it is infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that the Company's employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for the Company, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against the Company may obtain injunctive or other equitable relief, which could effectively block its ability to further develop and commercialize one or more of its 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 the Company's business. In the event of a successful infringement or other intellectual property claim against the Company, it 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 its affected products, which may be impossible or require substantial time and monetary expenditure. the Company 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, the Company may need to obtain licenses from third parties to advance its research or allow commercialization of its product candidates, and it has done so from time to time. It may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, the Company would be unable to further develop and commercialize one or more of its product candidates, which could harm its business significantly. It cannot provide any assurances that third party patents do not exist which might be enforced against its product candidates, resulting in either an injunction prohibiting its sales, or, with respect to its sales, an obligation on its 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 the Company's existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of the Company's common stock may decline. Such announcements could also harm its reputation or the market for future products, which could have a material adverse effect on the Company's business.

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

Competitors may infringe or otherwise violate its patents, the patents of its licensors or its other intellectual property rights. To counter infringement or unauthorized use or misappropriations, the Company 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 the Company or any of its 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 the Company's patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of the Company's patents at risk of being invalidated or interpreted narrowly and could put its 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 the Company such as claims asserting that its 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. The Company cannot be certain that there is no invalidating prior art, of which it and the patent examiner were unaware during prosecution. For any patents and patent applications that it licenses from third parties, the Company 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, it would lose at least part, and perhaps all, of the patent protection on its current or future product candidates. Such a loss of patent protection could harm its business.

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

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

Because of the expense and uncertainty of litigation, it may conclude that even if a third party is infringing its in-licensed patents, any patents that may be issued as a result of its 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 the Company or its stockholders. In such cases, the Company 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 the Company's ability to protect its 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 the Company 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 the Company's ability to obtain new patents or to enforce patents that the Company has licensed or that it 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 the Company's ability to obtain new patents or to enforce patents that the Company has licensed or that it may obtain in the future.

The Company may not be able to protect its intellectual property rights throughout the world, which could impair its business.

Filing, prosecuting, and defending patents covering OC-01 (varenicline) nasal spray, OC-02 and any future product candidate throughout the world would be prohibitively expensive. Competitors may use the Company's technologies in jurisdictions where it has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where it 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 the Company's products in such jurisdictions and take away the Company's market share where it does 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.

The Company's future reliance on third parties may require the Company to share its trade secrets, which increases the possibility that a competitor will discover them or that the Company's trade secrets will be misappropriated or disclosed.

Because the Company expects to rely on third parties to manufacture OC-01 (varenicline) nasal spray and any other product candidates, and it expects to collaborate with third parties on the continuing development of OC-01 (varenicline) nasal spray and any other product candidates, it must, at times, share trade secrets with them. The Company also expects to conduct R&D programs that may require it to share trade secrets under the terms of its partnerships or agreements with CROs. The

Company seeks to protect its 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 its 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 the Company's confidential information, including its 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 the Company's competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that the Company's proprietary position is based, in part, on its know-how and trade secrets, a competitor's discovery of the Company's trade secrets or other unauthorized use or disclosure would impair its competitive position and may have an adverse effect on business and results of operations.

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

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

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

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

The degree of future protection afforded by its intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect its business, or permit the Company to maintain its competitive advantage. The following examples are illustrative:

- others may be able to make formulations or compositions that are the same as or similar to the Company's current and future product candidates, but that are not covered by the claims of the patents that it owns;
- others may be able to make product that is similar to the Company's current and future product candidates it intends to commercialize that is not covered by the patents that the Company exclusively licensed and has the right to enforce;
- the Company, any of its future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that it owns;
- the Company or any of its future licensor might not have been the first to file patent applications covering certain of its inventions;
- others may independently develop similar or alternative technologies or duplicate any of the Company's technologies without infringing its intellectual property rights;
- it is possible that the Company's future patent applications will not lead to issued patents;
- issued patents that the Company owns may not provide it with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- the Company's 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 it does not have patent rights, and then use the information learned from such activities to develop competitive products for sale in the Company's major commercial markets; and
- the Company may not develop additional proprietary technologies that are patentable.

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

Any future collaborations that the Company enters into may not be successful. The success of its collaboration arrangements will depend heavily on the efforts and activities of its 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 the Company's 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 the Company's 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;
- the Company could grant exclusive rights to its collaborators that would prevent it from collaborating with others;
- collaborators may not properly maintain or defend its intellectual property rights or may use its intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate its intellectual property or proprietary information or expose the Company to potential liability;
- disputes may arise between the Company and a collaborator that causes the delay or termination of the research, development or commercialization of its 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 the Company's products that results from its collaborating with them, and in such cases, it 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 the Company's future trademarks and trade names are not adequately protected, then it may not be able to build name recognition in markets of interest and its business may be adversely affected.

The Company intends to use registered or unregistered trademarks or trade names to brand and market itself and its products. The Company's trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. The Company may not be able to protect its rights to these trademarks and trade names, which it needs to build name recognition among potential partners or customers in the markets of interest. At times, competitors may adopt trade names or trademarks similar to the Company's, thereby impeding its 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 the Company's registered or unregistered trademarks or trade names. Over the long term, if the Company is unable to establish name recognition based on its trademarks and trade names, then it may not be able to compete effectively and its business may be adversely affected. The Company may license its trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how trademarks and trade names may be used, a breach of these agreements or misuse of such trademarks and tradenames by the Company's licensees may jeopardize its rights in or diminish the goodwill associated with its trademarks and trade names. The Company efforts to enforce or protect its 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 its business, growth prospects, operating results and financial condition.

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

The Company currently and may in the future license from third parties certain intellectual property relating to current and future product candidates. If the Company breaches any material obligations, or uses the intellectual property licensed to it in an unauthorized manner, it may be required to pay damages and the licensor may have the right to terminate the license, which could result in it 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, the Company's license agreement with Pfizer can be terminated by Pfizer upon 60 days’ written notice for the Company's uncured material breach or 30 days following non-payment or immediately upon the Company's insolvency.

Disputes may arise between the Company and its 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 the Company's technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the Company's right to sublicense patents and other rights to third parties;
- the Company's diligence obligations with respect to the use of the licensed technology in relation to its development and commercialization of its product candidates, and what activities satisfy those diligence obligations;
- its 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 the Company's licensors and the Company and its partners.

If disputes over intellectual property that the Company licenses prevents or impairs its ability to maintain its licensing arrangements on acceptable terms, it may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on the Company's business.

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

Further, the Company or its 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, it may miss potential opportunities to strengthen its patent position. It is possible that defects of form in the preparation or filing of the Company's 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 the Company or its 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 the Company's current or future licensors are not fully cooperative or disagree with it 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 the Company's 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 the Company's ability to prevent competition from third parties, which may have an adverse impact on its business.

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

The Company's acquired technologies and current or future licensed technology may be subject to retained rights. The Company's predecessors or licensors may retain certain rights under their agreements with the Company, 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 the Company's predecessors or future licensors limit their use of the technology to these uses, and it could incur substantial expenses to enforce its rights to the Company's licensed technology in the event of misuse.

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

Risks Related to Government Regulation

If the FDA does not conclude that OC-01 (varenicline) nasal spray 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 the Company expects, 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.

The Company submitted an NDA for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease in December 2020. The Company is seeking FDA approval through the Section 505(b)(2) regulatory pathway for OC-01 (varenicline) nasal spray. 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. The Company's 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 its ability to demonstrate the relevance to OC-01 (varenicline) nasal spray.

In particular, the Company 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 the Company's conclusions from ZEN or the data required for approval of its Section 505(b)(2) NDA are different than anticipated, the Company 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 its proposed timeline. Such delays could result in new competitive products reaching the market faster than OC-01 (varenicline) nasal spray, which could materially adversely impact the Company's 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 the Company is ultimately unable to obtain regulatory approval for its product candidates, it will be unable to generate product revenue and its 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 the Company's data is insufficient for approval and require additional preclinical, clinical or other data. Even if the Company eventually completes clinical testing and receives approval of any regulatory filing for its product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve its product candidates for a more limited indication or a narrower patient population than it originally requested. For example, the fact that OC-01 (varenicline) nasal spray did not achieve certain secondary endpoints in ONSET-2 could have an adverse effect on the Company's ability to obtain its desired label for OC-01 (varenicline) nasal spray, if approved. The Company has not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of its existing product candidates or any product candidates it may seek to develop in the future will ever obtain regulatory approval.

Further, development of the Company's product candidates and/or regulatory approval may be delayed for reasons beyond its control. For example, a U.S. federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018 and 2019, or diversion of resources to currently handle the SARS-CoV-2 virus pandemic public health emergency and pandemic 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 the Company's ability to progress development of its product candidates or obtain regulatory approval for its product candidates. In addition, the impact of SARS-CoV-2 virus pandemic may cause the FDA to allocate additional resources to product candidates focused on treating related illnesses, which could lead to longer approval processes for the Company's product candidates. Moreover, some of the Company's analyses of the ONSET-2 clinical trial data are post-hoc analyses and, although it believes that these post-hoc analyses can provide additional information regarding results from this clinical trial, retrospective analyses can result in the introduction of bias and may be given less weight by the FDA, including for purposes of determining whether to accept the Company's NDA for filing or approving its NDA. Finally, the Company's competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that its product candidates, or the clinical trials that support their approval, contain deficiencies. Such actions by its competitors could delay or even prevent the FDA from approving any of the Company's NDAs.

Applications for the Company's 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 the Company's clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that the Company's product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude the Company's 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 the Company seeks approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the Company's interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of the Company's 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;

- the Company 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 the Company contracts 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 the Company's clinical data insufficient for approval.

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

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

In the United States, the European Union and other jurisdictions there have been a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect the Company's 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 the product candidates. The Company 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 the Company is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if it is unable to maintain regulatory compliance, it may lose any marketing approval that may have been obtained and the Company 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 (or collectively, the ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact 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.

There remain judicial, Congressional and executive branch challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed several 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, several 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 (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." The 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax.

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. Additionally, 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 back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when the Supreme Court will make a decision. Although the United States Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to

review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is also unclear how such litigation and other efforts to repeal and replace the ACA and the healthcare reform measures of the Biden administration will impact the ACA and the Company's 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 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) and other COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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 the Company's product candidates, if approved, and accordingly, the 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’s budget proposal for the fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. In addition, the Trump administration previously released a “Blueprint” to lower drug prices and reduce out-of-pocket costs of prescription drugs that contained 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. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA also released a final rule, on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. In addition, on November 20, 2020, CMS issued an interim final rule implementing President Trump’s Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives.

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.

The Company expects 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 the Company receives for any approved product. It is possible that additional governmental action is taken in response to address the SARS-CoV-2 virus pandemic. 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 the Company from being able to generate revenue, attain profitability or commercialize its product candidates.

In the European Union, similar political, economic and regulatory developments may affect the Company's ability to profitably commercialize its 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 the Company's 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 the Company's product candidates, restrict or regulate post-approval activities and affect its ability to commercialize its 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. The Company cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, particularly in light of the recent presidential election, or what the impact of such changes on the marketing approvals of the Company's 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 the Company to more stringent product labeling and post-marketing testing and other requirements.

The Company's 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.

The Company is exposed to the risk that its 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 the Company's reputation. Although the Company has adopted a code of business conduct and ethics with respect to its employees, agents and contractors, it is not always possible to identify and deter misconduct by these parties, and the precautions the Company takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, the Company is a 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 the Company, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on 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 its operations.

If the Company fails to comply with environmental, health and safety laws and regulations, it could become subject to fines or penalties or incur costs that could have a material adverse effect on its business.

The Company and any contract manufacturers and suppliers it engages 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. Its operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Its operations also produce hazardous waste. The Company generally contracts with third parties for the disposal of these materials and wastes. It cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from the Company's use of hazardous materials, it could be held liable for any resulting damages, and any liability could exceed its resources. Under certain environmental laws, it could be held responsible for costs relating to any contamination at the Company's current or past facilities and at third party facilities. It 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 the Company's research, product development and manufacturing efforts. In addition, it cannot entirely eliminate the risk of accidental injury or contamination from these materials or waste. Although the Company maintains workers’ compensation insurance to cover it for costs and expenses it may incur due to injuries to its employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. It does not currently maintain insurance for environmental liability or toxic tort claims that may be asserted against the Company in connection with storage or disposal of hazardous and flammable materials, including chemicals and biological materials. Accordingly, in the event of contamination or injury, it could be held liable for damages or be penalized with fines in an amount exceeding its resources,

and its clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on business, financial condition, results of operations and growth prospects.

In addition, the Company 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 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 the Company's product candidates in one jurisdiction does not mean that it will be successful in obtaining regulatory approval of its 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 the Company's product candidates in one jurisdiction does not guarantee that it 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 the Company intends to charge for its 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 the Company and could delay or prevent the introduction of its products in certain countries. If the Company or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, its target market will be reduced and ability to realize the full market potential of its product candidates will be harmed.

In addition, the Company 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 the Company's business plan, and which may result in its product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

The Company's business activities are subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries in which it operates, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit the Company's ability to compete in foreign markets and subject it to liability if it violates them.

The Company recently completed a trial and may plan to initiate additional trials in countries other than the United States. The Company's business activities are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which it operates. 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. The Company's 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, its dealings with these prescribers and purchasers are subject to regulation under the FCPA. 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 the Company's employees, agents or contractors, or those of its 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 the Company, its officers or its employees, the closing down of its facilities,

requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of the Company's business. Any such violations could include prohibitions on the Company's ability to offer its products in one or more countries and could materially damage its reputation, its brand, international activities, its ability to attract and retain employees and its business, growth prospects, operating results and financial condition.

In addition, the Company's 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 its products, or its failure to obtain any required import or export authorization for the Company's products, when applicable, could harm its international sales and adversely affect its revenue. Compliance with applicable regulatory requirements regarding the export of the Company's products may create delays in the introduction of its products in international markets or, in some cases, prevent the export of its 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 the Company fails to comply with export and import regulations and such economic sanctions, it 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 its products by, or in its decreased ability to export products to existing or potential customers with international operations. Any decreased use of the Company's products or limitation on its ability to export or sell access to its products would likely adversely affect the Company's business.

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

If any of the Company's product candidates are approved and the Company is found to have improperly promoted off-label uses of those products, it 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 the Company's 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 the Company receives marketing approval for OC-01 (varenicline) nasal spray as a treatment for the signs and symptoms of dry eye disease, physicians may nevertheless use the product for their patients in a manner that is inconsistent with the approved label. If the Company is found to have promoted such off-label uses, it 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 the Company cannot successfully manage the promotion of its product candidates, if approved, it could become subject to significant liability, which would materially adversely affect business, growth prospects, operating results and financial condition.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns 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 the Company's business may rely, which could negatively impact its 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, and other events that may otherwise affect the FDA’s ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which the Company's 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 the Company's 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.

Separately, in response to the SARS-CoV-2 virus pandemic, in March 2020, the FDA announced its intention to postpone most domestic and foreign inspections of manufacturing facilities and products and only restarted domestic inspections on a risk-based basis in July 2020. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the SARS-CoV-2 virus pandemic. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process the Company's regulatory submissions, which could have a material adverse effect on its business. Further, in the Company's operations as a public company, future government shutdowns could impact its ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

Business disruptions could seriously harm the Company's future revenue and financial condition and increase its costs and expenses.

Company's operations, and those of its 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 the Company's control that can disrupt business. The occurrence of any of these business disruptions could seriously harm the Company's operations and financial condition and increase its costs and expenses. For example, the Company relies on third party manufacturers to produce and process its product candidates. The Company's ability to obtain supplies of its 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 the Company's operations including its corporate headquarters are located in a single location in Princeton, New Jersey. Damage or extended periods of interruption to its corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause the Company to cease or delay development of some or all of its product candidates. Although the Company maintains property damage and business interruption insurance coverage on these facilities, the insurance might not cover all losses under such circumstances and Company's business may be seriously harmed by such delays and interruption.

Risks Related to Reliance on Third Parties

The Company relies on third parties to conduct its clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

The Company does not have the ability to independently conduct its clinical trials. The Company currently relies on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct its current and potential future clinical trials of OC-01 (varenicline) nasal spray and other product candidates, and the Company expects to continue to rely upon third parties to conduct additional clinical trials of OC-01 (varenicline) nasal spray and other product candidates. Third parties have a significant role in the conduct of its clinical trials and the subsequent collection and analysis of data. These third parties are not the Company's employees, and except for remedies available to the Company under its agreements with such third party, it has limited ability to control the amount or timing of resources that any such third party will devote to the Company's clinical trials. Some of these third parties may terminate their engagements with the Company at any time. If it needs to enter into alternative arrangements with a third party, it would delay the Company's development activities.

The Company's reliance on these third parties for such development activities will reduce its control over these activities but will not relieve it of its regulatory responsibilities. For example, the Company will remain responsible for ensuring that each of its clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires the Company 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 the Company to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If the Company or any of its CROs fail to comply with applicable GCP requirements, the clinical data generated in the clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require the Company to perform additional clinical trials before approving its marketing applications. The Company cannot provide assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of its clinical trials comply with GCP regulations. In addition, the clinical trials must be conducted with product produced under current cGMP regulations. The Company's failure to comply with these regulations may require it to repeat clinical trials, which would delay the marketing approval process. The Company also is 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 the Company relies on for these services may also have relationships with other entities, some of which may be its competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct the Company's clinical trials in accordance with regulatory requirements or the Company's stated protocols, it will not be able to obtain, or may be delayed in obtaining, marketing approvals for its product candidates and will not be able to, or may be delayed in its efforts to, successfully commercialize its product candidates.

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

The Company does not currently have the infrastructure or internal capability to manufacture supplies of its product candidates for use in development and commercialization. It relies, and expects to continue to rely, on third party manufacturers

for the production of its product candidates for preclinical studies and clinical trials under the guidance of members of its organization. The Company does not have long-term supply agreements. If it were to experience an unexpected loss of supply of OC-01 (varenicline) nasal spray and other product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, the Company could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

The Company expects to continue to rely on third party manufacturers for the commercial supply of any of its product candidates for which it obtains marketing approval. It may be unable to maintain or establish required agreements with third party manufacturers or to do so on acceptable terms. Even if it is 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 the Company's product candidates according to its schedule, or at all, including if its third party contractors give greater priority to the supply of other products over its product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between the Company and them;
- the termination or nonrenewal of arrangements or agreements by the Company's third party contractors at a time that is costly or inconvenient for the Company;
- the breach by the third party contractors of the Company's 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 the Company's product candidates according to its 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 the Company's proprietary information, including its trade secrets and know-how.

The Company does not have complete control over all aspects of the manufacturing process of, and is dependent on, 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 contract manufacturers cannot successfully manufacture material that conforms to the Company's 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, the Company does not have control over the ability of its 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 its product candidates or if it withdraws any such approval in the future, the Company may need to find alternative manufacturing facilities, which would significantly impact its ability to develop, obtain marketing approval for or market its product candidates, if approved. The Company's failure, or the failure of its 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 the Company's product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of the Company's product candidates and harm its business and results of operations.

The Company currently relies on single source manufacturers and suppliers for OC-01 (varenicline) nasal spray. If it decides 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 the Company's product candidates.

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

The Company may pursue collaborations with third parties for the development or commercialization of its product candidates. If it decides to pursue collaborations, but is not able to establish those collaborations on commercially reasonable terms, it may have to alter its development and commercialization plans. If it does enter into collaborations that are not successful, it may not be able to capitalize on the market potential of these product candidates.

The Company's development programs and the potential commercialization of its product candidates will require substantial additional cash to fund expenses. It may seek to selectively form collaborations to expand its capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these

relationships may require the Company to incur non-recurring and other charges, increase its near and long-term expenditures, issue securities that dilute its existing stockholders, or disrupt management and business.

The Company would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether it reaches a definitive agreement for a collaboration will depend, among other things, upon the Company's 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 the Company's 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 the Company for its product candidate. Further, the Company may not be successful in its 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 the Company is successful in entering into a collaboration, the terms and conditions of that collaboration may restrict it from entering into future agreements on certain terms with potential collaborators.

If and when the Company seeks to enter into collaborations, it may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If the Company is unable to do so, it may have to curtail the development of a product candidate, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales and marketing activities, or increase expenditures and undertake development or commercialization activities at its own expense. If the Company elects to increase its expenditures to fund development or commercialization activities on its own, it may need to obtain additional capital, which may not be available to the Company on acceptable terms or at all. If the Company does not have sufficient funds, it may not be able to further develop its product candidates or bring them to market and generate product revenue.

The Company's business operations and current and future relationships with healthcare professionals, clinical investigators, consultants, patient organizations, customers, CROs and third party payors in connection with its 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 the Company 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 the Company obtains marketing approval. The Company's current and future arrangements with healthcare professionals, including ECPs, clinical investigators, CROs, third party payors and customers may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which the Company markets, sells and distributes its products for which it obtains 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. Moreover, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, 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, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws 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 FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- 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, state and local laws that require the registration of pharmaceutical sales representatives;
- 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;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding their payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiology assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- 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, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous 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.

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. Certain state and local jurisdictions require the registration of pharmaceutical sales representatives. State, federal 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 EU 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 the Company's responsibility and liability in relation to personal data that it processes and it may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if the Company's efforts to comply with GDPR or other applicable EU laws and regulations are not successful, it could adversely affect its business in the EU.

Efforts to ensure that the Company's 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 the Company's 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 the Company's 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 the Company's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, 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 the Company's operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if the Company is successful in defending against

any such actions that may be brought against it, its business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom the Company expects 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

The Company will need substantial additional funding in the future. If it is unable to raise capital when needed, or on acceptable terms, it may be forced to delay, reduce and/or eliminate one or more of its 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. The Company's operations have consumed significant amounts of cash since inception, and it expects its expenses to increase in connection with ongoing activities, particularly as it continues to conduct clinical trials of, and seek marketing approval for, OC-01 (varenicline) nasal spray and other product candidates. Even if one or more of the product candidates that the Company develops is approved for commercial sale, including OC-01 (varenicline) nasal spray, it anticipates incurring significant costs associated with commercializing any approved product candidate. The Company's expenses could increase beyond expectations if the Company is required by the FDA, the EMA or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that it currently anticipates. Other unanticipated costs may also arise. Because the design and outcome of its planned and anticipated clinical trials are highly uncertain, it cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate it develops.

As of December 31, 2020, the Company had $192.6 million in cash and cash equivalents. Although the Company believes that its available cash and cash equivalents will be sufficient to fund its 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 the Company could use its available capital resources sooner than it currently expects. Changing circumstances, some of which may be beyond its control, could cause the Company to consume capital significantly faster than it currently anticipates, and it may need to seek additional funds sooner than planned.

Advancing the development of OC-01 (varenicline) nasal spray and other product candidates will require a significant amount of capital. The Company's 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 (varenicline) nasal spray and other product candidates. It will continue to require additional capital to develop its product candidates and fund operations for the foreseeable future. The Company 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 stockholders or restrict operating activities. The amount of additional capital the Company will need to raise will depend on many factors, including:

- the scope, timing, rate of progress and costs of the Company's drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for its product candidates;
- the number and scope of clinical programs the Company decides to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of its product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing of the Company's product candidates, if they receive marketing approval;
- the extent to which the Company acquires or in-licenses other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing the Company's intellectual property rights and defending intellectual property-related claims;
- the Company's ability to establish and maintain collaborations on favorable terms, if at all;
- the Company's efforts to enhance operational systems and its ability to attract, hire and retain qualified personnel, including personnel to support the development of its product candidates and, ultimately, the sale of its products, following FDA approval;
- the Company implementation of operational, financial and management systems; and
- any current or future potential effects of the SARS-CoV-2 virus pandemic on the Company's business, operations, preclinical and clinical development and commercialization timelines and plans; and
- the costs associated with being a public company.

The Company does not have any committed external source of funds. Adequate additional financing may not be available on acceptable terms, or at all. The Company's failure to raise capital as and when needed or on acceptable terms would have a negative impact on the Company's business, growth prospects, operating results and financial condition and its ability to

pursue business strategy, and the Company may have to delay, reduce the scope of, suspend or eliminate one or more of its research-stage programs, clinical trials or future commercialization efforts.

An active trading market for the Company's common stock may not be sustained.

Although the Company's common stock is listed on the NASDAQ Global Select Market, the market for the Company's shares has demonstrated varying levels of trading activity. The Company cannot predict the prices at which its 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 the Company's ability to raise capital.

The price of the Company's stock may be volatile, and investors could lose all or part of their investment.

The trading price of the Company's common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which it cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, has 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, including the potential impacts of the SARS-CoV-2 virus pandemic, may negatively affect the market price of the Company's common stock, regardless of its 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 the Company's product candidates or those of its competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to the Company's products or its competitors' products;
- actual or anticipated changes in the Company's growth rate relative to its 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 the Company or its 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 the Company;
- 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 the Company's shares;
- announcement or expectation of additional financing efforts;
- sales of the Company's common stock by the Company, its insiders or other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

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

Sales of a substantial number of shares of the Company's common stock in the public market could cause its stock price to fall.

Holders of an aggregate of 14,193,281 shares of the Company's common stock have rights, subject to certain conditions, to require it to file registration statements covering their shares or to include their shares in registration statements that the Company may file for itself or other stockholders. Sales of a substantial number of shares of the Company's common stock in the public market, 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 the Company's common stock. In addition, the Company has filed a registration statement on Form S-8 registering 5,822,484 shares of common stock that it may issue under its 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 and volume limitations applicable to affiliates.

Raising additional capital may cause dilution to the Company's existing stockholders, restrict its operations or require the Company to relinquish rights to its product candidates on unfavorable terms to the Company.

The Company 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 it raises additional capital through the sale of equity or convertible debt or equity securities, investors' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect their 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 the Company's business. If the Company raises additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, it may have to relinquish valuable rights to its product candidates or grant licenses on terms that are not favorable to it. In addition, the Company may seek additional capital due to favorable market conditions or strategic considerations even if it believes it has sufficient funds for its current or future operating plans.

The Company's principal stockholders and management own a significant percentage of Company's stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2020, the Company's executive officers, directors, holders of 5% or more of the Company's capital stock and their respective affiliates beneficially owned approximately 73% of its 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 the Company's 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 the Company's common stock that investors may feel are in their best interest as one of the Company's stockholders. The interests of this group of stockholders may not always coincide with other stockholders' interests 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 the Company's common stock.

The Company is an "emerging growth company," and it cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make the Company's common stock less attractive to investors.

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). For as long as it continues to be an emerging growth company, it intends 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 the Company's 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 the Company's 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.

The Company cannot predict if investors will find its common stock less attractive because the Company may rely on these exemptions. If some investors find the Company's common stock less attractive as a result, there may be a less active trading market for common stock and the Company's stock price may be more volatile.

The Company will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which it has more than $1.07 billion in annual revenue; (2) the date it qualifies as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (3) the date on which it has 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 its 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. The Company has irrevocably elected not to avail itself 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 the Company's business could significantly affect its financial position and results of operations.

The Company has been incurring increased costs as a result of operating as a public company, and its management is required to devote substantial time to compliance initiatives and corporate governance practices. Additionally, if the Company fails to maintain proper and effective internal control over financial reporting, its ability to produce accurate financial statements on a timely basis could be impaired.

The Company is 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. Company's management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, to comply with these rules and regulations, the Company has incurred and will continue to incur legal, accounting and financial compliance costs, and these expenses may increase even more after it is no longer an "emerging growth company".

In addition, the Company has been and will be required to incur costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with this Annual Report, the Company is required to make a formal assessment of the effectiveness of the Company's internal control over financial reporting, and once it ceases to be an emerging growth company, it will be required to include an attestation report on internal control over financial reporting issued by the Company's independent registered public accounting firm. As disclosed in the annual report on Form 10-K for the year ended December 31, 2019, the Company identified two material weaknesses in its internal control over financial reporting. Management identified certain measures necessary to strengthen the internal control over financial reporting and to address the material weaknesses, and implemented them in the fourth quarter of 2019 and throughout 2020. The Company has remediated the material weaknesses and management has determined that, as of December 31, 2020, the internal controls were designed and operating effectively and have been operating effectively for a sufficient period for management to conclude that the material weaknesses have been remediated. These efforts to document, evaluate, remediate and maintain the Company's internal control over financial reporting, has been and will continue to be both costly and challenging. In this regard, it will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of its 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.

If the Company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is unable to maintain proper and effective internal control over financial reporting, it may not be able to produce timely and accurate financial statements. If that were to happen, the market price of the Company's stock could decline and it could be subject to sanctions or investigations by the stock exchange on which the common stock is listed, the SEC or other regulatory authorities.

The Company does not intend to pay dividends on its common stock so any returns will be limited to the value of the stock.

The Company has never declared or paid any cash dividends on its common stock. The Company currently anticipates that it will retain future earnings for the development, operation and expansion of its business and does 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 the Company's restated certificate of incorporation and restated bylaws and Delaware law might discourage, delay or prevent a change in control of the Company or changes in its management and, therefore, depress the market price of its common stock.

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

- establish a classified board of directors so that not all members of the Company's 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 the Company's stockholders;
- authorize the issuance of “blank check” preferred stock that the board could use to implement a stockholder rights plan (also known as a poison pill);
- eliminate the ability of the 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 the stockholders;
- prohibit cumulative voting;
- authorize the board of directors to amend the bylaws;

- establish advance notice requirements for nominations for election to the Company's 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 Company's 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 the Company's 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 stockholders to receive a premium for their shares of the Company's capital stock and could also affect the price that some investors are willing to pay for Company's common stock.

The Company's 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 the Company and its stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with the Company or its directors, officers or employees.

The Company's 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 the Company's behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against the Company arising under the DGCL, its amended and restated certificate of incorporation or its amended and restated bylaws; and
- any action asserting a claim against the Company 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 the Company or its directors, officers or other employees, which may discourage lawsuits against the Company and its directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of the Company's securities shall be deemed to have notice of and consented to this provision. If a court were to find this exclusive-forum provision in the Company's amended and restated bylaws to be inapplicable or unenforceable in an action, the Company may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm its business. Nothing in the Company's 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.

General Risk Factors

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

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

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

The market price of the Company's 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. The Company may be the target of this type of litigation in the future. Securities litigation against the Company could result in substantial costs and divert management's attention from other business concerns, which could seriously harm Company's business.

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

The Company has designed its disclosure controls and procedures to reasonably assure that information it must disclose in reports it files or submits 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. The Company believes 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 the Company's control system, misstatements due to error or fraud may occur and not be detected.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

The Company's corporate headquarters are currently located in Princeton, New Jersey, where it leases 12,007 square feet of office space pursuant to an amended lease agreement that expires on June 30, 2022. In February 2021, the Company entered into a lease agreement for laboratory and office space in New Jersey for a three-year term beginning on March 1, 2021 and ending on February 29, 2024. Total future minimum lease payments under this agreement are $0.4 million.

ITEM 3. LEGAL PROCEEDINGS

None.

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

The Company's 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 the Company's common stock.

Holders of Common Stock

As of January 31, 2021, there were approximately 70 holders of record of the Company's common stock. The approximate number of holders is based upon the actual number of holders registered in the Company's 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

The Company has never declared or paid any cash dividends on its common stock and does not anticipate paying cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data below should be read in conjunction with the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected financial data set forth below is derived from the Company's audited financial statements and may not be indicative of future operating results.

	Year Ended December 31,	
	2020	2019
	(in thousands, except per share data)	
Statements of Operations and Comprehensive Loss Data:		
Operating expenses:		
Research and development	$ 39,811	$ 33,628
Selling, general and administrative	31,178	13,673
Total operating expenses	70,989	47,301
Loss from operations	(70,989)	(47,301)
Other income, net	469	1,590
Net loss and comprehensive loss	$ (70,520)	$ (45,711)
Net loss per share, basic and diluted	$ (2.92)	$ (9.97)

	As of December 31,	
	2020	2019
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 192,585	$ 139,147
Working capital [(1)]	185,385	136,781
Total assets	197,910	143,209
Total liabilities	11,251	5,911
Total stockholders' equity	$ 186,659	$ 137,298

[(1)] Working capital is defined 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 the Company's financial condition and results of operations should be read in conjunction with the Company's 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 the Company's plans and strategy for its 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, the Company's 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."

The discussion and analysis below has been organized as follows:

- Executive Summary, including a description of the business and significant events that are important to understanding the results of operations and financial condition;
- Results of operations, including an explanation of significant differences between the periods in the specific line items of the statements of operations;
- Financial condition addressing the Company's liquidity position, sources and uses of cash, capital resources and requirements, commitments, and off-balance sheet arrangements; and
- Critical accounting policies which are most important to both the portrayal of the Company's financial condition and results of operations.

Executive Summary

Introduction and Overview

Oyster Point Pharma, Inc. is a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases. The Company's lead product candidate OC-01 (varenicline) nasal spray, 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. Based on OC-01 (varenicline) nasal spray's clinical trial results and its novel mechanism of action, the Company believes OC-01 (varenicline) nasal spray, if approved by the FDA, has the potential to become the new standard of care and redefine how dry eye disease is treated for millions of patients.

The Company has no products approved for sale and has not generated revenue since its inception in 2015. The Company expects to finance its operations through private and public equity or debt financing, collaborative or other arrangements with corporate sources or through other sources of financing.

Since its formation in June 2015, the Company has devoted substantially all of its resources to developing its product candidates. The Company has incurred significant operating losses to date. The Company's net losses were $70.5 million and $45.7 million for the year ended December 31, 2020 and 2019, respectively. As of December 31, 2020, the Company had an accumulated deficit of $154.8 million. The Company expects that its operating expenses will increase as it advances its product candidates through preclinical and clinical development, seeks regulatory approval, and prepares for and, if approved, proceeds to commercialization; acquires, discovers, validates and develops additional product candidates; obtains, maintains, protects and enforces its intellectual property portfolio; and hires additional personnel. In addition, the Company has incurred and will continue to incur additional costs associated with operating as a public company.

The Company plans to continue to use third party service providers, including CROs and CMOs, to carry out its preclinical and clinical development and to manufacture and supply the materials to be used during the development and commercialization of its product candidates.

Recent Events

Submission of the NDA for OC-01 (varenicline) *nasal spray to FDA*

On December 17, 2020, the Company submitted a 505(b)(2) NDA to the FDA for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease. The MYSTIC, ONSET-1 and ONSET-2 clinical trials showed statistically significant improvements in Schirmer's Score (an objective, reproducible, and quantifiable measure of natural tear film production), as compared to control, which was the primary endpoint in all studies. Key secondary endpoints in ONSET-1 and ONSET-2 included change from baseline in symptoms as assessed by eye dryness score. In both of these pivotal studies, there was statistically or nominally statistically significant improvement in symptom scores at Day 28, and in ONSET-2 as early as Day 14, as compared to control. All doses studied in the clinical trial program were well-tolerated with no serious drug related adverse events.

Submission of the Phase 2 clinical trial protocol for Neurotrophic Keratopathy (NK) to the FDA

On November 30, 2020, the Company submitted to the FDA a protocol to initiate a clinical study in adult patients with NK, a degenerative disease characterized by decreased corneal sensitivity and poor corneal healing. The submission was made to the Company's IND application for OC-01 (varenicline) nasal spray in dry eye disease. NK is the second of a number of important potential indications the Company is evaluating for OC-01 (varenicline) nasal spray, illustrating the Company's commitment to treating unmet needs related to ocular surface diseases. Enrollment of the first patient in the OLYMPIA Phase 2 study in NK is planned for the first half of 2021.

Entry into $100 million At-the-Market Sales Agreement (ATM) with Cowen and Company, LLC

On November 5, 2020, the Company entered into an at-the-market sales agreement (or ATM) with Cowen and Company, LLC, pursuant to which the Company may offer and sell shares of the Company's common stock having an aggregate offering price of up to $100 million. The ATM was entered into by the Company concurrently with a registration statement on Form S-3. Under the registration statement, the Company may offer and sell, in one or more offerings, up to an aggregate of $300 million of any combination of securities registered thereunder, consisting of shares of common and preferred stock, debt securities and warrants.

The Impact of the SARS-CoV-2 Virus Pandemic

In March 2020, the World Health Organization declared the SARS-CoV-2 virus outbreak to be a pandemic. Also, in March of 2020, due to the SARS-CoV-2 virus pandemic, the Company experienced an impact at select clinical trial sites where ophthalmology practices were closed, or subjects were unable to attend visits, or where clinical trial sites did not feel comfortable putting their staff or subjects into a Controlled Adverse Environment (CAE®), which limited the Company's ability to assess the related secondary endpoint in its ONSET-2 study for those subjects. The Company then conducted a further post-hoc analysis on the data, which led to the discovery of additional treatment benefits in the 1.2 mg/ml dose group that were not captured with the statistical method used for analysis of the secondary endpoint.

During the year ended December 31, 2020, financial results of the Company were not significantly affected by the SARS-CoV-2 virus pandemic. However, the extent to which the SARS-CoV-2 virus outbreak affects the Company's future financial results and operations will depend on future developments which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the outbreak, and current or future domestic and international actions to contain it and treat it. The Company continues to evaluate the impact of the SARS-CoV-2 virus pandemic on its trials, expected timelines and costs, as well as potential supply-chain challenges as it prepares itself for commercialization of the OC-01 (varenicline) nasal spray candidate and as it continues to learn more about the impact of the SARS-CoV-2 virus pandemic on the industry.

The Company continues to evaluate and develop pipeline candidates for the potential treatment of various medical indications. The ongoing SARS-CoV-2 virus pandemic may impact access to supplies necessary to conduct preclinical studies, cause delay to the timelines to initiate or complete *in vitro* or *in vivo* animal studies, or indirectly impact the operation of contract organizations that are necessary for the Company to advance preclinical projects. If the SARS-CoV-2 virus pandemic continues and persists for an extended period of time, the Company could experience significant disruptions to its clinical development timelines, which could adversely affect its business, financial condition and results of operations.

The ultimate impact of the SARS-CoV-2 virus pandemic or a similar health epidemic is highly uncertain and subject to change. The Company has taken a variety of measures in an effort to ensure the availability and functioning of the Company's

critical infrastructure and to promote the safety and security of its employees. These measures include requiring remote working arrangements for employees, which will continue through at least the second quarter of 2021 and investing in personal protective equipment for the future return to the office. In addition, Company management is continuously evaluating and developing an implementation plan for employees' safe return to the office once that option becomes feasible. The Company will continue to actively monitor the evolving situation related to the SARS-CoV-2 virus pandemic and may take further actions that alter its operations, including those that may be required by federal, state or local authorities, or that the Company determines are in the best interests of its employees, partners and other third-parties with whom the Company does business. At this point, the full extent to which the SARS-CoV-2 virus pandemic may affect the Company's business, operations, preclinical and clinical development and commercialization timelines and plans, including the resulting impact on its expenditures and capital needs, remains uncertain.

For further discussion of the risks that the Company faces as a result of the SARS-CoV-2 virus pandemic refer to Part II, Item 1A, Risk Factors, of this Annual Report on Form 10-K.

Components of Operating Results

Revenue

The Company did not generate any revenue from product sales in 2020 or 2019.

Operating Expenses

Research and Development Expenses

The Company's research and development expenses consist of expenses incurred in connection with the development of its product candidates. These expenses consist primarily of:

- fees paid to third parties to conduct certain research and development activities on the Company's behalf and consulting costs;
- certain payroll-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expense for employees dedicated to the Company's research and product development (payroll-related expense);
- costs related to acquiring and manufacturing clinical trial materials and costs for manufacturing of pre-approval inventory of the product candidates under development;
- costs for laboratory supplies, product acquisition and license costs; and
- costs related to regulatory compliance requirements.

The Company expenses both internal and external research and development expenses as they are incurred.

The Company does not allocate its costs by product candidate, as a significant amount of research and development expenses includes internal costs, such as payroll and other personnel expenses, laboratory supplies, and external costs, such as fees paid to third parties to conduct research and development activities on the Company's behalf. Several of the Company's 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 Company tracks its research and development expenses by type of activity: clinical and preclinical, chemistry, manufacturing and controls (CMC), and other costs.

The Company is focusing substantially all of its resources on the development of its product candidates, particularly OC-01 (varenicline) nasal spray. The Company expects its research and development expenses to increase for at least the next few years, as it seeks to initiate additional clinical trials for its product candidates, complete its clinical programs, and prepare for the potential regulatory approval of these product candidates. Predicting the timing or cost to complete the Company's clinical programs or validation of its commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of the Company's control. For example, if the FDA or other regulatory authorities were to require the Company to conduct clinical trials beyond those that it currently anticipates, the Company could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, the Company is unable to predict when or if its product candidates will receive regulatory approval with any certainty.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of the following:

- certain payroll-related expenses, including salaries, bonuses, employee benefits and stock-based compensation expense (payroll-related expense);
- professional fees for legal, consulting, accounting and tax services, as well as insurance expense;
- commercial planning expenses, marketing and promotional expense;
- rent, office equipment, and utilities;
- information technology costs; and
- and other general operating expenses not otherwise classified as research and development expenses.

The Company anticipates that its selling, general and administrative expenses will increase as a result of increased personnel costs, commercial planning expenses, expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the applicable stock exchange and SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Other Income, Net

Other income, net consists primarily of interest income earned on money market funds, which are included in cash and cash equivalents on the Company's balance sheets.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

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

	Year Ended December 31,			
	2020	**2019**	**$ Change**	**% Change**
Research and development:				
Clinical, preclinical	$ 12,265	$ 13,550	$ (1,285)	(9)%
Chemistry, manufacturing and controls (CMC)	19,476	13,145	6,331	48 %
Other	8,070	6,933	1,137	16 %
Total research and development	39,811	33,628	6,183	18 %
Selling, general and administrative	31,178	13,673	17,505	128 %
Loss from operations	(70,989)	(47,301)	(23,688)	50 %
Other income, net	469	1,590	(1,121)	(71)%
Net loss	$ (70,520)	$ (45,711)	$ (24,809)	54 %

Research and Development Expenses

Research and development expenses increased by $6.2 million during the year ended December 31, 2020 compared to the year ended December 31, 2019. The Company's clinical, preclinical expense was $1.3 million lower in 2020 primarily due to the completion of the ONSET-2 Phase 3 clinical trial in May 2020. The Company incurred higher CMC expense in the amount of $6.3 million primarily due to the continued advancement of OC-01 (varenicline) nasal spray, as well as higher employee headcount, which resulted in an increase in payroll-related expenses. Other research and development expense increased by $1.1 million. The increase was due to higher costs primarily related to data management and regulatory costs in connection with the advancement of the OC-01 (varenicline) nasal spray and NDA submission in the amount of $3.2 million, as well as a $2.9 million fee paid to the FDA in connection with the NDA submission in December of 2020. This increase was partially offset by the $5 million license payment to Pfizer in 2019, as further described in Note 9, *Commitments and Contingencies.*

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $17.5 million during the year ended December 31, 2020 compared to the year ended December 31, 2019. The increase was primarily driven by additional payroll-related expenses of $9.0 million due to an increase in headcount, higher other general and administrative expenses of $5.5 million due to expansion of the Company's organization, as well as additional costs incurred by the Company due to operating as a publicly traded company. The Company incurred higher commercial planning expenses of $3.1 million in anticipation of a U.S. launch of OC-01 (varenicline) nasal spray, if approved by the FDA, in the fourth quarter of 2021.

Other Income, Net

Other income, net decreased by $1.1 million during the year ended December 31, 2020 compared to the year ended December 31, 2019, primarily due to a lower rate of return on money market funds earned during the period.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2020 and December 31, 2019, the Company had cash and cash equivalents of $192.6 million and $139.1 million, respectively.

On November 5, 2020, the Company entered into an at-the-market sales agreement (or ATM) with Cowen and Company, LLC, pursuant to which the Company may offer and sell shares of the Company's common stock having an aggregate offering price of up to $100 million. The ATM was entered into by the Company concurrently with a registration statement on Form S-3. Under the registration statement, the Company may offer and sell, in one or more offerings, up to an aggregate of $300 million of any combination of securities registered thereunder, consisting of shares of common and preferred stock, debt securities and warrants.

On May 19, 2020, the Company completed a follow-on public offering selling 4,312,500 shares of common stock at a price to the public of $28.00 per share. The net proceeds from the offering were $112.6 million.

Future Funding Requirements

Based on the current business plan, management believes that its available cash and cash equivalents will be sufficient to fund the Company's planned operations for at least 12 months from the filing date of this Annual Report on Form 10-K.

On December 17, 2020, the Company submitted a 505(b)(2) NDA to the FDA for its first lead product candidate, OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease. The Company expects to incur sales and marketing expenses with the commercialization of OC-01 (varenicline) nasal spray, if approved for sale, as well as increased research and development expenses as it develops additional product candidates. Since inception, the Company has incurred recurring losses and negative cash flows from operations. The Company generated net losses of $70.5 million and $45.7 million for the years ended December 31, 2020 and 2019, respectively, and had an accumulated deficit of 154.8 million as of December 31, 2020. The Company has historically financed its operations primarily through the sale and issuance of its securities. In addition, the Company has incurred and will continue to incur additional costs associated with operating as a public company. The Company does not expect to generate any meaningful revenue unless and until it obtains regulatory approval of and commercializes any of its product candidates or decides to enter into collaborative agreements with third parties. The Company is subject to all of the risks typically related to the development of new product candidates, and it may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. The Company will continue to require additional capital to continue developing its product candidates and fund operations for the foreseeable future. The Company may seek to raise capital through private or public equity or debt financings, collaborative or other arrangement with corporate sources, or through other sources of financing. The Company anticipates that it 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 the Company's drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for the Company's product candidates;
- the number and scope of clinical programs the Company decides to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of the Company's product candidates;

- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing of the Company's product candidates, if they receive marketing approval;
- the extent to which the Company acquires or in-licenses other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing the Company's intellectual property rights and defending intellectual property-related claims;
- the Company's ability to establish and maintain collaborations on favorable terms, if at all;
- its efforts to enhance operational systems and the Company's ability to attract, hire and retain qualified personnel, including personnel to support the development of the Company's product candidates and, ultimately, the sale of the Company's products, following FDA approval;
- the Company's implementation of operational, financial and management systems; and
- any current or future potential effects of the SARS-CoV-2 virus pandemic on the Company's business, operations, preclinical and clinical development and commercialization timelines and plans; 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 the Company's product candidates could significantly change the costs and timing associated with the development of that product candidate.

Furthermore, the Company's operating plans may change in the future, and it will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If additional funds are raised by issuing equity securities, the Company's stockholders may experience dilution. Any future debt financing into which the Company might enter may impose upon it additional covenants that restrict the Company's operations, including limitations on its ability to incur liens or additional debt, pay dividends, repurchase its common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that it raises may contain terms that are not favorable to the Company or its stockholders.

Adequate funding may not be available to the Company on acceptable terms or at all, and any uncertainty and volatility in capital markets caused by the SARS-CoV-2 virus pandemic may negatively impact the availability and cost of capital. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce, or terminate some or all of its development programs and clinical trials or may also be required to sell or license to others rights to its product candidates in certain territories or indications that it would prefer to develop and commercialize itself. If the Company is required to enter into collaborations and other arrangements to supplement its funds, it may have to give up certain rights that limit its ability to develop and commercialize the product candidates or may have other terms that are not favorable to the Company or its stockholders, which could materially affect its business and financial condition. See the section of this Annual Report on Form 10-K titled “Risk Factors” for additional risks associated with the Company's substantial capital requirements.

Cash Flow Discussion

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,		
	2020	2019	$ Change
Net cash (used in) provided by:			
Operating activities	$ (58,399)	$ (40,815)	$ (17,584)
Investing activities	(700)	(200)	(500)
Financing activities	112,547	174,985	(62,438)
Net increase in cash, cash equivalents and restricted cash	$ 53,448	$ 133,970	$ (80,522)

Cash Flows Used in Operating Activities

Net cash used in operating activities increased by $17.6 million for the year ended December 31, 2020 compared to the year ended December 31, 2019, due to higher net loss adjusted for non-cash items, partially offset by an increase in working capital of $3.2 million driven primarily by the timing of payments to the Company's service providers. The Company's higher net loss was driven by the continued development of the Company's product candidates, as well as costs incurred in connection with the NDA submission for OC-01 (varenicline) nasal spray in December 2020.

Cash Flows Used in Investing Activities

Net cash used in investing activities increased by $0.5 million for the year ended December 31, 2020 compared to the year ended December 31, 2019, primarily related to payments for equipment to be used in the manufacturing of OC-01 (varenicline) nasal spray.

Cash Flows Provided by Financing Activities

Net cash provided by financing activities decreased by $62.4 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. The decrease was primarily due to the lower net proceeds generated from the Company's follow-on equity offering in May 2020 compared to the net proceeds received from the Company's IPO in November 2019 and from the issuance of redeemable preferred stock in February and April 2019.

Contractual Obligations and Commitments

The following table summarizes the Company's contractual obligations as of December 31, 2020 (in thousands):

	Payments Due by Period		
	Less than 1 year	1 to 3 years	Total
Operating lease obligations [1]	$ 432	$ 255	$ 687
Finance lease obligations [2]	$ 18	$ 20	$ 38

[1] The Company leases office facilities in Princeton, New Jersey under two non-cancellable operating leases with an expiration date July 31, 2022. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.
[2] The Company leases certain office equipment under finance leases with expiration dates in August 2022 and August 2023.

In February 2021, the Company entered into a lease agreement for laboratory and office space in New Jersey for a three-year term beginning on March 1, 2021 and ending on February 29, 2024. Total future minimum lease payments under this agreement are $0.4 million.

In October 2019, the Company entered into a non-exclusive patent license agreement with Pfizer (License Agreement), which granted the Company non-exclusive rights under Pfizer’s patent rights covering varenicline tartrate to develop, manufacture, and commercialize the Company's OC-01 (varenicline) nasal spray product candidate. Under the terms of the

License Agreement, the Company made an upfront payment to Pfizer of $5.0 million. If the Company successfully commercializes OC-01 (varenicline) nasal spray, it may be required to pay a single milestone payment in low double-digit millions and tiered royalties on net sales of OC-01 (varenicline) nasal spray 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 (varenicline) nasal spray 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

The Company's financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires the application of appropriate technical accounting rules and guidance as well as the use of 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. These estimates are based on the Company's historical experience and on various other factors that it believes 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. The Company's significant accounting policies are summarized in Item 15 — Note 1, *Nature of Business, Basis of Presentation and Significant Accounting Policies,* to the Financial Statements. The Company identifies its most critical accounting policies as those that are the most pervasive and important to the portrayal of the Company's financial position and results of operations, and that require the most difficult, subjective and/or complex judgments by management regarding estimates about matters that are inherently uncertain. The future effects of the SARS-CoV-2 virus pandemic on the Company's results of operations, cash flows, and financial position are unclear, however the Company believes it has used reasonable estimates and assumptions in preparing the interim condensed financial statements. The Company's critical accounting policies include stock-based compensation, accrued research and development expense, and income taxes.

Stock-Based Compensation

Prior to the IPO, the fair value of the Company’s common stock underlying the stock options was determined by the BOD with assistance from management and, in part, on input from an independent third-party valuation firm. The BOD 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 mid-point between the vesting date and the end of the contractual term.

Expected volatility. As the Company has a limited trading history of its common stock, the expected volatility is estimated based on the third quartile of the range of the observed volatilities for comparable publicly traded biotechnology and pharmaceutical related companies over a period equal to the expected term of the stock option grants. The comparable companies are chosen based on industry, stage of development, size and financial leverage of potential comparable companies.

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.

Accrued Research and Development Expense

The Company is a party to various agreements with CMOs and CROs. 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, the Company 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. Actual results could differ from estimates.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, using the asset and liability method whereby deferred tax asset and liability amounts are determined based on the differences between the financial reporting and tax bases of assets and liabilities. The differences are measured using the enacted tax rates and laws that are in effect for the year in which they 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 assesses 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 the Company 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. 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. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Off-Balance Sheet Arrangements

Since the Company's inception, the Company has not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012 (JOBS Act) permits an “emerging growth company” such as Oyster Point Pharma, Inc. to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. However, the Company has chosen to irrevocably “opt out” of such extended transition period, and as a result, it 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. The Company intends 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.

The Company will remain an emerging growth company until the earliest to occur of: (1) the last day of its first fiscal year in which it has total annual revenues of more than $1.07 billion; (2) the date it qualifies as a “large accelerated filer,” with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which it has 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 its initial public offering.

Recent Accounting Pronouncements

For a summary of recently issued accounting guidance applicable to the Company, see Item 15 — Note 1, *Nature of Business, Basis of Presentation and Significant Accounting Policies,* to the Financial Statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

The market risk inherent in the Company's financial instruments and in its financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. As of December 31, 2020, the Company had cash equivalents of $192.6 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 the Company's 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 the Company's future interest income.

The Company does not believe that inflation, interest rate changes or foreign currency exchange rate fluctuations have had a significant impact on its 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, 2020, management, with the participation of the Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

Remediation of Material Weaknesses as disclosed in the Form 10-K for the year ended December 31, 2019

As disclosed in the annual report on Form 10-K for the year ended December 31, 2019, the Company identified two material weaknesses in its internal control over financial reporting.

The first material weakness identified was that the Company did not design or maintain an effective control environment commensurate with the financial reporting requirements. Specifically, the Company 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 the Company 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.

Management identified the people and processes necessary to strengthen the internal control over financial reporting and to address the material weaknesses. The Company began implementing certain of these measures in the fourth quarter of 2019 and continued to develop remediation plans and implemented additional measures throughout 2020. The Company has remediated the material weaknesses through the following actions:

- Hired additional accounting and finance personnel with an appropriate level of accounting knowledge and experience to ensure proper analysis, recording and disclosure of accounting matters in an accurate and timely manner;
- Evaluated and designed controls to address the preparation and review of account reconciliations and journal entries;
- Designed and implemented month-end processes, accounting policies, procedures, and controls to assist in the preparation and review of complete, accurate and timely financial accounting, reporting and disclosures; and
- Implemented and adopted formal accounting policies and procedures.

Management has completed its design, testing and evaluation of the enhanced and newly implemented internal controls and determined that as of December 31, 2020, the controls were designed and operating effectively and have been operating effectively for a sufficient period for management to conclude that the material weaknesses have been remediated.

Changes in Internal Control over Financial Reporting

Other than the actions taken to improve the Company's internal control over financial reporting as summarized above, there have been no changes in the internal control over financial reporting during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well designed 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. 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 its inherent limitations, misstatements due to error or fraud may occur and not be detected.

Management's Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of the Company's management, with the participation of the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting as of December 31, 2020 based on the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation under the framework in Internal Control — Integrated Framework (2013), the Company's management concluded that its internal control over financial reporting was effective as of December 31, 2020.

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 the Company's definitive proxy statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after December 31, 2020 (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. FINANCIAL STATEMENTS, SCHEDULES, EXHIBITS

(a) (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: see Exhibit Index submitted as a separate section of this report

(b) Exhibits

See Exhibit Index submitted as a separate section of this report

(c) Not applicable

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, 2020 and 2019, 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, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 18, 2021

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, 2020	December 31, 2019
ASSETS		
Current Assets		
Cash and cash equivalents	$ 192,585	$ 139,147
Prepaid expenses and other current assets	3,782	3,033
Total current assets	196,367	142,180
Property and equipment, net	804	181
Restricted cash	61	51
Right-of-use assets, net	678	797
Total assets	$ 197,910	$ 143,209
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 2,279	$ 507
Accrued expenses and other current liabilities	8,285	4,596
Lease liabilities	418	296
Total current liabilities	10,982	5,399
Lease liabilities, non-current	269	512
Total Liabilities	11,251	5,911
Commitments and Contingencies (Note 9)		
Stockholders' Equity		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized; none outstanding	—	—
Common stock, $0.001 par value per share; 1,000,000,000 shares authorized, 25,890,490 and 21,366,950 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	26	21
Additional paid-in capital	341,384	221,508
Accumulated deficit	(154,751)	(84,231)
Total Stockholders' Equity	186,659	137,298
Total Liabilities and Stockholders' Equity	$ 197,910	$ 143,209

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,	
	2020	**2019**
Operating expenses:		
Research and development	$ 39,811	$ 33,628
Selling, general and administrative	31,178	13,673
Total operating expenses	70,989	47,301
Loss from operations	(70,989)	(47,301)
Other income, net	469	1,590
Net loss and comprehensive loss	$ (70,520)	$ (45,711)
Net loss per share, basic and diluted	$ (2.92)	$ (9.97)
Weighted average shares outstanding, basic and diluted	24,128,603	4,585,146

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
	Shares	Amount	Shares	Amount			
Balance at January 1, 2019	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 $146	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
Issuance of common stock upon exercise of stock options	—	—	11,703	—	31	—	31
Stock-based compensation	—	$ —	—	$ —	$ 3,266	$ —	$ 3,266
Balance at December 31, 2019	—	—	21,366,950	21	221,508	(84,231)	137,298
Net loss			—	—	—	(70,520)	(70,520)
Issuance of common stock upon follow-on equity offering, net of issuance costs of $8,125	—	—	4,312,500	5	112,620	—	112,625
Issuance of common stock upon exercise of stock options	—	—	175,030	—	283	—	283
Issuance of common stock upon vesting of restricted stock units (RSUs)			36,010	—	—	—	—
Stock-based compensation expense	—	—		—	6,973	—	6,973
Balance at December 31, 2020	—	$ —	25,890,490	$ 26	$ 341,384	$ (154,751)	$ 186,659

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,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (70,520)	$ (45,711)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,973	3,266
Depreciation	77	19
Reduction in the carrying amount of the right-of-use assets	384	166
Changes in assets and liabilities:		
Prepaid expenses and other assets	(381)	(2,623)
Accounts payable	1,773	38
Change in lease liabilities	(382)	(151)
Accrued expenses and other current liabilities	3,677	4,181
Net cash used in operating activities	(58,399)	(40,815)
Cash flows from investing activities		
Capital expenditures	(700)	(200)
Net cash used in investing activities	(700)	(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 follow-on equity offering, net of issuance costs	112,625	—
Payments of deferred offering costs	(361)	—
Proceeds from the issuance of common stock upon exercise of stock options	283	31
Net cash provided by financing activities	112,547	174,985
Net increase in cash, cash equivalents and restricted cash	53,448	133,970
Cash, cash equivalents and restricted cash at the beginning of the period	$ 139,198	$ 5,228
Cash, cash equivalents and restricted cash at the end of the period	$ 192,646	$ 139,198
Supplemental cash flow information		
Right-of-use for office space and office equipment acquired through leases	$ 320	$ 897
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. Nature of Business, Basis of Presentation and Significant Accounting Policies

Description of the Business

Oyster Point Pharma, Inc. (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. From inception through December 31, 2020, the Company has been primarily engaged in business planning, research, clinical development of its therapeutic product candidates, recruiting and raising capital.

On December 17, 2020, the Company submitted a 505(b)(2) NDA to the FDA for its first lead product candidate, OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry disease. The Company expects to incur increased sales and marketing expenses with the commercialization of OC-01 (varenicline) nasal spray, if approved for sale, as well as increased research and development expenses as it develops additional product candidates. Since inception, the Company has incurred recurring losses and negative cash flows from operations. The Company generated net losses of $70.5 million and $45.7 million for the years ended December 31, 2020 and 2019, respectively, and had an accumulated deficit of $154.8 million as of December 31, 2020. The Company has historically financed its operations primarily through the sale and issuance of its securities.

The Company completed its initial public offering (IPO) in November 2019 selling 5,750,000 shares of common stock raising aggregate net proceeds from the offering in the amount of $82.1 million. On May 19, 2020, the Company completed a follow-on equity offering selling 4,312,500 shares of common stock at a price of $28.00 per share. The net proceeds from the offering were $112.6 million. For further discussion on changes in the Company's capital structure, see Note 5, *Stockholders' Equity.*

The Company had cash and cash equivalents of $192.6 million as of December 31, 2020. 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 filing date of this Annual Report on Form 10-K.

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).

Use of Estimates

The preparation of financial statements in conformity with 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 as of the date of the financial statements. 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. 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.

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 FDA 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 and there can be no assurance that the Company will be able to secure such additional financing on a timely basis, if at all, that will be sufficient to meet these needs. 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, Cash Equivalents, and Restricted Cash

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, 2020 and 2019, cash and cash equivalents consisted of cash on deposit with a bank denominated in U.S. dollars and investment in money market funds.

The following table provides a reconciliation of cash, cash equivalents and restricted cash within the consolidated balance sheets that sum to the total of the same such amounts shown in the statements of cash flows (in thousands):

	Year ended December 31,	
	2020	**2019**
Cash and cash equivalents	$ 192,585	$ 139,147
Restricted cash [(a)]	61	51
Cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 192,646	$ 139,198

[(a)] — Held in a separate bank account to support a letter of credit agreement related to the Company's office leases, which expire 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. Construction-in-progress reflects amounts incurred for property and equipment construction or improvements that have not yet been placed in service and are not depreciated or amortized. Repairs and maintenance are expensed when incurred. Upon retirement or sale, the cost of the assets disposed of and the related accumulated depreciation are removed from the accounts, and any resulting gain or loss is included in the determination of net loss.

Estimated useful lives by major asset category are as follows:

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

Long-lived assets are tested for recoverability whenever events or circumstances indicate that the carrying amount may not be recoverable.

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 and finance lease assets are included in right-of-use assets, net, and the current and non-current portions of the finance and operating lease liabilities are included in lease liabilities, and lease liabilities, non-current, respectively, on the balance sheets.

Right-of-use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the lease commencement date. 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. For finance leases, right of use assets are amortized on a straight-line basis over the shorter of the lease term or the estimated useful life of the leased assets. The Company accounts for lease and non-lease components as a single lease component for operating leases. The discount rate used to calculate the present value of the Company's leases is based on either an explicit rate stipulated in the contract (for finance leases) or the 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 is 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 determines 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. The Company does not record leases with terms of 12 months or less on the balance sheets. See Note 8, *Leases,* for additional information regarding the Company's operating and finance leases.

Fair Value of Financial Instruments

The carrying amounts for financial instruments consisting of cash equivalents, restricted cash, accounts payable and accrued liabilities approximate their fair value due to short-term maturities. See Note 2, *Fair Value Measurements,* for additional information on the Company's measurements of its financial instruments.

Research and Development

Research and development expenses primarily consist of CMOs and CROs related costs, costs relating to manufacturing clinical trial materials and pre-approval inventory, regulatory compliance costs, employee compensation and benefits, consulting, laboratory supplies, product licenses, sponsored research, as well as 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.

Net Loss per Common Share

Basic and diluted net loss per common share is presented in conformity with ASC Topic 260, Earning Per Share for all periods presented. In accordance with this guidance, basic and diluted net loss per common share is determined by dividing the net loss by the weighted-average number of common shares outstanding during the period. Basic net loss per share is calculated without consideration of potentially dilutive securities, while diluted net loss per share accounts for potentially dilutive securities outstanding for the period.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718. 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.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, using the asset and liability method whereby deferred tax asset and liability amounts are determined based on the differences between the financial reporting and tax bases of assets and liabilities. The differences are measured using the enacted tax rates and laws that are in effect for the year in which

they 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 assesses 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 the Company 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. 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. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that would result from transactions and economic events other than those with 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.

Reclassification

Certain prior year amounts have been reclassified for comparative purposes.

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

ASU 2019-12 — In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, or Topic 740, as amended, which simplifies 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. Early adoption is permitted. The Company adopted ASU 2019-12 in the second quarter of 2020 and its adoption did not have a material effect on the Company's financial statements and related disclosures.

ASU 2018-15 — In August 2018, the FASB issued ASU 2018-15, *Intangibles - Goodwill and Other (Subtopic 350): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract,* or Topic 350, as amended, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. For public companies, this ASU is effective for interim and annual reporting periods beginning after December 15, 2019. Early adoption is permitted. The Company adopted ASU 2018-15 effective January 1, 2020 and its adoption did not have a material effect on the Company's financial statements and related disclosures.

ASU 2018-13 — In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, or Topic 820, as amended, 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 adopted ASU 2018-13 effective January 1, 2020 and its adoption did not have a material effect on the Company's financial statements and related disclosures.

Recently issued accounting pronouncements not yet adopted

ASU 2020-10 — In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The amendments in the ASU 2020-10 are effective for annual periods beginning after December 15, 2020, for public business entities. The Company plans to adopt ASU 2020-10 on January 1, 2021 and does not expect that the adoption of this update to have a material effect on the Company's consolidated financial statements.

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.

As of December 31, 2020, financial assets measured and recognized at fair value were as follows (in thousands):

	Fair Value Measurements at December 31, 2020			
	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	$ 191,585	$ —	$ —	$ 191,585
Total fair value of assets	$ 191,585	$ —	$ —	$ 191,585

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

Money market funds are included in cash and cash equivalents on the Company's balance sheets. They are valued using quoted market prices and therefore are classified within Level 1 of the fair value hierarchy.

The carrying amounts reflected in the Company's balance sheets for cash and cash equivalents, prepaid expenses and other current assets, restricted cash, accounts payable and accrued expenses and other liabilities approximate their fair values due to their short-term nature.

There were no financial liabilities measured and recognized at fair value as of December 31, 2020 and December 31, 2019.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk, such as money market funds, are included in cash and cash equivalents on the balance sheets. The Company attempts to minimize the risks related to cash and

cash equivalents by using highly-rated financial institutions that invest in a broad and diverse range of financial instruments. The Company's investment portfolio is maintained in accordance with its investment policy that defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer.

3. Property and Equipment, Net

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

	December 31,	
	2020	2019
Leasehold improvements	$ 158	$ 105
Office equipment	68	45
Furniture and fixtures	73	50
Construction-in-progress	601	—
Total property and equipment	900	200
Accumulated depreciation	(96)	(19)
Property and equipment, net	$ 804	$ 181

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2020	2019
Accrued compensation	$ 3,500	$ 1,214
Accrued professional services	1,244	1,163
Accrued research and development expense	3,541	2,219
Accrued expenses and other current liabilities	$ 8,285	$ 4,596

5. Stockholders' Equity

Common Stock

The Company is authorized 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 for future issuance as follows:

	December 31,	
	2020	2019
Outstanding options under the 2016 Plan	2,567,566	2,748,434
Outstanding options under the 2019 Plan	918,145	29,466
Equity awards available for grant under the 2019 Plan	1,790,106	2,747,047
Unvested restricted stock units (RSUs) under the 2019 Plan	61,215	23,125
Shares reserved for purchase under the ESPP [(a)]	270,000	270,000
Total	5,607,032	5,818,072

[(a)] — Employee Stock Purchase Plan approved in October 2019, as further described in Note 6, *Equity Incentive Plans*.

Changes in Capital Structure

On May 19, 2020, the Company completed a follow-on public offering selling 4,312,500 shares of common stock at a price to the public of $28.00 per share. The net proceeds from the offering were $112.6 million.

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, 2020 and December 31, 2019, there were no shares of redeemable convertible preferred stock issued and outstanding.

In October 2019, the Company effected a 2.832861-for-1 reverse stock split of the Company's common stock and redeemable convertible preferred stock. 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 for the period through October 18, 2019 have been retroactively adjusted to give effect to the reverse stock split.

On February 15, 2019, the Company executed the Series B Preferred Stock Purchase Agreement to sell 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.

6. Equity Incentive Plans

In October 2019, the Company's Board of Directors (BOD) and stockholders approved the 2019 Equity Incentive Plan (the 2019 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 incentive stock option (ISO) and non-qualified stock option (NSO) shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the BOD. 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 BOD. To date, outstanding options have a term of 10 years and generally vest over a four-year period with 25% vested after the first year and monthly vesting thereafter.

In October 2019, the Company's BOD and stockholders 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, 2020 and 2019, respectively.

Stock Options

The following table summarizes stock option activity under the 2016 Plan and the 2019 Plan during the year ended December 31, 2020 (in thousands, except share, contractual term and per share data):

	Outstanding Options			
	Number of Shares Underlying Outstanding Options	Weighted- Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2020	2,777,900	$ 4.59	8.7	$ 55,146
Options granted	891,529	28.22		—
Options exercised	(175,030)	1.62		4,370
Options canceled	(8,688)	20.02		91
Outstanding at December 31, 2020	3,485,711	$ 10.74	8.2	$ 36,506
Vested and exercisable as of December 31, 2020	1,556,245	$ 3.46	7.5	$ 23,914
Vested and expected to vest as of December 31, 2020	3,485,711	$ 10.74	8.2	$ 36,506

During the years ended December 31, 2020 and 2019, the Company granted options with a weighted-average grant date fair value of $20.41 and $8.62 per share, respectively. The fair value of options that vested during the years ended December 31, 2020 and 2019 was $3.2 million and $2.5 million, respectively. As of December 31, 2020, the total unrecognized stock-based compensation expense for stock options was $21.6 million, which is expected to be recognized over a weighted average period of 3.0 years.

Restricted Stock Units

The company issues restricted stock units (RSUs) with terms of one year to three years, subject to continuing services to be provided to the Company. The value of an RSU award is based on the Company's stock price on the date of the grant.

Activity with respect to the Company's restricted stock units during the year ended December 31, 2020 was as follows (in thousands, except share, contractual term, and per share data):

	Outstanding RSUs			
	Number of Shares Underlying Outstanding Units	Weighted Average Grant Date Fair Value per Unit	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2020	23,125	$ 16.00	2.8	$ 565
Restricted stock units granted	74,100	27.01		2,001
Restricted stock units vested	(36,010)	25.34		811
Restricted stock units canceled	—	—		—
Outstanding at December 31, 2020	61,215	$ 23.83	1.4	$ 1,152
Unvested and expected to vest as of December 31, 2020	61,215	$ 23.83	1.4	$ 1,152

During the years ended December 31, 2020 and 2019, the Company granted RSUs with a weighted-average grant date fair value of $27.01 and $16.00 per unit, respectively. The fair value of RSUs vested during the year ended December 31, 2020 was $0.9 million. No RSUs vested during the year ended December 31, 2019. As of December 31, 2020, the total unrecognized stock-based compensation expense for RSUs was $1.3 million, which is expected to be recognized over a weighted average period of 1.3 years.

Stock-Based Compensation Expense

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

	Year Ended December 31,	
	2020	2019
Research and development	$ 966	$ 579
Selling, general and administrative	6,007	2,687
Total stock-based compensation	$ 6,973	$ 3,266

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 BOD with assistance from management and, in part, on input from an independent third-party valuation firm. The BOD 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 mid-point between the vesting date and the end of the contractual term.

Expected volatility. As the Company has a limited trading history of its common stock, the expected volatility is estimated based on the third quartile of the range of the observed volatilities for comparable publicly traded biotechnology and pharmaceutical related companies over a period equal to the expected term of the stock option grants. The comparable companies are chosen based on industry, stage of development, size and financial leverage of potential comparable companies.

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,	
	2020	2019
Expected volatility	82.0% - 118.0%	69.0% - 84.0%
Risk-free interest rate	0.36% - 1.40%	1.48% - 2.38%
Dividend yield	—%	—%
Expected term	6.08 years	5.04 - 6.08 years

7. Net Loss Per Share

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

	Year Ended December 31,	
	2020	2019
Numerator:		
Net loss	$ (70,520)	$ (45,711)
Denominator:		
Weighted-average shares outstanding, basic and diluted	24,128,603	4,585,146
Net loss per share, basic and diluted	$ (2.92)	$ (9.97)

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

	December 31,	
	2020	2019
Options to purchase common stock	3,485,711	2,777,900
Unvested restricted stock units	61,215	23,125
Total	3,546,926	2,801,025

8. Leases

Lease Obligations

In April 2019, the Company entered into a non-cancelable operating lease for office space in Princeton, New Jersey, commencing on July 1, 2019, for a period of three years from the commencement date. In January 2020, the Company amended this lease to include additional office space, with the same terms as the original lease. Total future minimum lease payments under this amendment are $0.7 million as of December 31, 2020. The total lease payments required over the life of this lease are $1.2 million. The remaining lease term was 1.6 years as of December 31, 2020. Rent expense was $0.4 million and $0.2 million for the year ended December 31, 2020 and 2019, respectively. The Company's variable lease payments primarily consist of maintenance and other operating expenses from its real estate leases. Variable lease payments are excluded from the right of use assets and lease liabilities and are recognized in the period in which the obligation for those payments is incurred. The lease terms include the option to extend or terminate the lease for one additional period of three years. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

The Company leases certain office equipment under finance leases with remaining lease terms of 1.7 years to 2.3 years. At the commencement date, the Company determined the amount of lease liability using a discount rate of 3%, which management determined represents the rate implicit in the lease. Interest expense and amortization expense for the finance leases were immaterial for the years ended December 31, 2020 and 2019, respectively.

Supplemental balance sheet information for the leases is as follows (in thousands):

	December 31, 2020	December 31, 2019
Operating lease right-of-use asset	$ 644	$ 783
Finance lease right-of-use asset	34	14
Total right-of-use asset	$ 678	$ 797
Operating lease liabilities	$ 400	$ 290
Finance lease liabilities	18	6
Total lease liabilities	$ 418	$ 296
Operating lease liabilities, non-current	$ 250	$ 500
Finance lease liabilities, non-current	19	12
Total lease liabilities, non-current	$ 269	$ 512

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

As of December 31, 2020	Finance Leases	Operating Leases	Total
2021	$ 18	$ 432	$ 450
2022	16	255	271
2023	4	—	4
Total undiscounted cash flows	38	687	725
Less: imputed interest	(1)	(37)	(38)
Total lease liability	37	650	687
Less: current portion	(18)	(400)	(418)
Lease liability	$ 19	$ 250	$ 269

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

In February 2021, the Company entered into a lease agreement for laboratory and office space in New Jersey for a three-year term beginning on March 1, 2021 and ending on February 29, 2024. Total future minimum lease payments under this agreement are $0.4 million.

9. Commitments and Contingencies

License Agreement

The Company is party to a non-exclusive patent 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) nasal spray product. Under the terms of the agreement, the Company made an upfront payment to Pfizer of $5 million during the year ended December 31, 2019. If the Company commercializes OC-01 (varenicline) nasal spray, it may be

required to pay a single milestone payment in 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 would commence upon the first commercial sale of OC-01 (varenicline) nasal spray and 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. No milestone was achieved or probable to be achieved or royalties payable accrued as of December 31, 2020 and 2019.

Contingencies

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. There are no matters pending that the Company currently believes are reasonably possible or probable of having a material impact to the Company's business, consolidated financial condition, results of operations of cash flows.

10. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the for the years ended December 31, 2020 and December 31, 2019 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 had an effective tax rate of 0% for the years ended December 31, 2020 and 2019. 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,	
	2020	**2019**
Federal statutory income tax rate	21.0 %	21.0 %
State taxes (tax effected)	7.7 %	8.5 %
Research tax credit	1.7 %	3.3 %
Other permanent differences	0.3 %	(2.0)%
Change in valuation allowance	(30.7)%	(30.8)%
Provision for income taxes	— %	— %

The components of the Company’s net deferred tax assets and liabilities as of December 31, 2020 and 2019, were as follows (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 29,786	$ 12,454
Credits	3,836	2,408
Tangible and intangible assets	2,666	1,977
Lease liability	195	227
Stock compensation	1,737	253
Accruals and Reserves	840	36
Gross deferred tax assets	39,060	17,355
Less: Valuation allowance	(38,051)	(16,423)
Deferred tax assets, net of valuation allowance	1,009	932
Deferred tax liabilities:		
Prepaids	(817)	(708)
Right of use asset	(192)	(224)
Net deferred tax assets	$ —	$ —

Deferred Tax Assets and Valuation Allowance

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 full valuation allowance against its U.S. deferred tax assets. The Company's valuation allowance increased by $21.6 million and $10.7 million for the years ended December 31, 2020, and 2019, respectively. The increases to the Company's valuation allowance for both years related to the losses generated during the periods.

NOL Carryforwards

For the years ended December 31, 2020 and 2019, the Company had $120.6 million and $59.1 million of U.S. federal net operating losses, respectively. Certain U.S. federal net operating loss carryforwards will begin to expire, if not utilized, in 2035. Included in the U.S. federal net operating loss carryforwards are $116.1 million and $54.6 million as of December 31, 2020 and 2019, respectively, of net operating loss carryforwards, which are not subject to expiration. However, the deductibility of such net operating loss carryforwards will be limited in future years.

For the years ended December 31, 2020 and 2019, the Company had state net operating loss carryforwards of $123.9 million and $60.7 million, respectively which generally begin to expire 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 Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state laws. 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 in prior periods. However, the change is not expected to cause a material limitation on the Company's utilization of net operating loss carryforwards. Subsequent ownership changes may affect the limitation in future years. The Company is not in a taxable position and no net operating loss carryforwards have been utilized to date.

Research and Experimentation Credit Carryforwards

As of December 31, 2020 and 2019, the Company had federal research and experimentation credit carryforwards of $3.3 million and $2.1 million, respectively, and state research and experimentation credit carryforwards of $0.7 million and

$0.4 million. The federal research and experimentation credit carryforwards expire beginning in the years 2037, and the state credit carryforwards are subject to varying expiration periods, the earliest beginning in year 2032.

Uncertain Tax Positions

As of December 31, 2020 and 2019, the Company had the following unrecognized tax benefits (in thousands):

	Year Ended December 31,	
	2020	2019
Balance at the beginning of the year	$ 5,388	$ 1,989
Increases for tax positions taken during prior period	50	—
Increases for tax positions taken during current period	—	3,399
Balance at the end of the year	$ 5,438	$ 5,388

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 files income tax returns in the U.S. federal, California, Florida, Massachusetts 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. If and when the Company claims net operating loss carryforwards from any prior year against future taxable income, those losses may be examined by the taxing authorities. As of December 31, 2020, there were no ongoing examinations.

11. Unaudited Quarterly Financial Information

Below is a summary of the unaudited quarterly financial information for the year ended December 31, 2020 (in thousands, except share and per share data):

	Three months ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Operating expenses:				
Research and development	$ 11,340	$ 8,554	$ 8,210	$ 11,707
Selling, general and administrative	5,589	6,940	8,112	10,537
Total operating expenses	16,929	15,494	16,322	22,244
Loss from operations	(16,929)	(15,494)	(16,322)	(22,244)
Other income, net	410	30	17	12
Net loss and comprehensive loss	$ (16,519)	$ (15,464)	$ (16,305)	$ (22,232)
Basic and diluted net loss per share	$ (0.77)	$ (0.66)	$ (0.63)	$ (0.86)
Weighted average shares outstanding	21,367,532	23,442,530	25,797,282	25,869,601

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
Selling, 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)
Other income, net	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

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

EXHIBIT INDEX

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.	10-K	001-39112	4.1	February 27, 2020
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.				
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 18, 2021 By: /s/ Jeffrey Nau

Jeffrey Nau, Ph.D., M.M.S.
President, Chief Executive Officer and President

Date: February 18, 2021 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 18, 2021
/s/ Daniel Lochner Daniel Lochner	Chief Financial Officer (Principal Financial and Accounting Officer)	February 18, 2021
/s/ Ali Behbahani Ali Behbahani, M.D.	Chair of the Board	February 18, 2021
/s/ Michael Atieh Michael Atieh	Director	February 18, 2021
/s/ Mark Murray Mark Murray	Director	February 18, 2021
/s/ William J. Link William J. Link, Ph.D.	Director	February 18, 2021
/s/ Clare Ozawa Clare Ozawa, Ph.D.	Director	February 18, 2021
/s/ Benjamin Tsai Benjamin Tsai	Director	February 18, 2021
/s/ Aimee Weisner Aimee Weisner	Director	February 18, 2021

Exhibit 10.9

OYSTER POINT PHARMA, INC.
OUTSIDE DIRECTOR COMPENSATION POLICY

(Adopted on January 21, 2021, effective as of the 2021 Annual Meeting)

Oyster Point Pharma, Inc. (the "**Company**") believes that the granting of equity and cash compensation to its members of the Board of Directors (the "**Board**," and members of the Board, "**Directors**") represents a powerful tool to attract, retain and reward Directors who are not employees of the Company ("**Outside Directors**"). This Outside Director Compensation Policy (the "**Policy**") is intended to formalize the Company's policy regarding cash compensation and grants of equity to its Outside Directors. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given such term in the Company's 2019 Equity Incentive Plan (the "**Plan**"). Outside Directors will be solely responsible for any tax obligations they incur as a result of the equity and cash payments received under this Policy.

1. CASH COMPENSATION

The following annual cash compensation for Outside Directors is payable quarterly in arrears on a prorated basis.

REGULAR MEETINGS OF THE BOARD

Annual compensation for the general services of Outside Directors is as follows:

Outside Director	$	40,000	Cash Annual Retainer
Chairman of the Board	$	75,000	Cash Annual Retainer

AUDIT COMMITTEE

Annual compensation for Audit Committee members is as follows:

Chairman of Committee	$	20,000	Cash Annual Retainer
Committee Members	$	10,000	Cash Annual Retainer

COMPENSATION COMMITTEE

Annual compensation for the Compensation Committee is as follows:

Chairman of Committee:	$	15,000	Cash Annual Retainer
Committee Members	$	6,000	Cash Annual Retainer

There are no per meeting attendance fees for attending Compensation Committee meetings.

NOMINATING AND CORPORATE GOVERNANCE COMMITTEE
Compensation for the Nominating and Corporate Governance Committee is as follows:

Chairman of Committee:	$	10,000	Cash Annual Retainer
Committee Members:	$	5,000	Cash Annual Retainer

For clarity, each Outside Director who serves as the chair of a committee will receive only the annual fee as the chair of the committee and not the additional annual fee as a member of the committee, provided that the Outside

Director who serves as the Chairman of the Board will receive the annual fee as the Chairman of the Board and the annual fee as an Outside Director.

2. EQUITY COMPENSATION

Outside Directors will be entitled to receive all types of Awards (except Incentive Stock Options) under the Plan, including discretionary Awards not covered under this Policy. All grants of Awards to Outside Directors pursuant to Sections (b) and (c) of this Policy will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

(a) No Discretion. No person will have any discretion to select which Outside Directors will be granted Annual Awards (as defined below) under this Policy or to determine the number of Shares to be covered by such Awards (except as provided in subsection (e) below).

(b) Initial Awards. Upon first joining the Board (such date, the "**Start Date**"), each Outside Director will be automatically granted the following awards:

(1) an award of Restricted Stock Units and Non-Statutory Stock Options with a combined Value of 0.08% of the total number of shares outstanding as of the grant date (the "**Initial Award**"). The Non-Statutory Stock Options will vest over three years (on the same day of the month as the Start Date) with 1/3 cliff vesting at 12 months and the remainder to vest at 1/24 per month and the Restricted Stock Units will vest over three years (on the same day of the month as the Start Date) with 1/3 vesting annually, in each case, subject to continued service as a Service Provider through each vesting date. The number of Non-Statutory Stock Options will be calculated by multiplying the total shares outstanding, as of the grant date, by 0.08% and multiplying the product by 50%. The number of Restricted Stock Units will be calculated by (a) multiplying the total shares outstanding, as of the grant date, by 0.08% and multiplying the product by 50% (the "**Initial Award RSU Quantity**") and (b) dividing the Initial Award RSU Quantity by 1.5, plus

(2) an award of Restricted Stock Units and Non-Statutory Stock Options equal to (A) the number of (i) Restricted Stock Units and (ii) Non-Statutory Stock Options, both subject to the Annual Award provided to Outside Directors at the last annual meeting of stockholders (the "**Annual Meeting**") *each multiplied by* (B) a fraction (i) the numerator of which is (x) 12 minus (y) the number of fully completed months between the date of the last Annual Meeting and the Start Date and (ii) the denominator of which is 12, rounded to the nearest unit (together the "**Additional Initial Award**"). The Additional Initial Award will vest on the same schedule as the Restricted Stock Units and Non-Statutory Stock Options subject to such other outstanding Annual Awards, but, in case, will vest fully on the date of the next Annual Meeting held after the date of grant if not fully vested on such date, in each case, subject to continued service as a Service Provider through each vesting date.

(c) Annual Awards.

(1) On the day following the Annual Meeting, each Outside Director (including the Chairman of the Board) will be automatically granted an award of Restricted Stock Units and Non-Statutory Stock Options with a combined Value of 0.04% of the total shares outstanding as of the annual meeting (the "**Annual Award**"). The Non-Statutory Stock Options will vest monthly as to 1/12th of the total Non-Statutory Stock Options subject to the Annual Award beginning on the first month following the grant date (on the same day of the month as the grant date) and the Restricted Stock Units will vest on the one year anniversary of the grant date, but, in each case, the Annual Award will vest fully on the date of the next Annual Meeting held after the date of grant if not fully vested on such date, in each case, subject to continued service as a Service Provider through each vesting date. The number of Non-Statutory Stock Options will be calculated by multiplying the total shares outstanding, as of the annual meeting, by 0.04% and multiplying the product by 50%. The number of Restricted Stock Units will be calculated by (a) multiplying the total shares outstanding, as of the annual meeting, by 0.04% and multiplying the product by 50% (the "**Annual Award RSU Quantity**") and (b) dividing the Annual Award RSU Quantity by 1.5.

(d) Value. For purposes of this Sections (b) and (c), "**Value**" means the fair value for financial accounting purposes on the date of grant, with the number of Shares of our Common Stock determined based on that Value, rounded down.

(e) Revisions. The Compensation Committee in its discretion may change and otherwise revise the terms of Initial Awards, Additional Initial Awards or Annual Awards granted under this Policy, including, without limitation, the number of Shares subject thereto, for Initial Awards, Additional Initial Awards or Annual Awards of the same or different type granted on or after the date the Compensation Committee determines to make any such change or revision.

3. CHANGE IN CONTROL

In the event of a Change in Control, each Outside Director will fully vest in his or her outstanding Company equity awards, including any Initial Award, Additional Initial Award or Annual Award, provided that the Outside Director continues to be a Service Provider through such date.

4. ANNUAL COMPENSATION LIMIT

No Outside Director may be paid, issued or granted, in any Fiscal Year, cash compensation and Awards with an aggregate value greater than $750,000 (with the value of each Award based on its Grant Value for purposes of the limitation under this Section 4). Any cash compensation paid or Awards granted to an individual for his or her services as an Employee, or for his or her services as a Consultant (other than as an Outside Director), will not count for purposes of the limitation under this Section 4.

5. TRAVEL EXPENSES

Each Outside Director's reasonable, customary and documented travel expenses to Board meetings will be reimbursed by the Company.

6. ADDITIONAL PROVISIONS

All provisions of the Plan not inconsistent with this Policy will apply to Awards granted to Outside Directors.

7. ADJUSTMENTS

In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under this Policy, will adjust the number of Shares issuable pursuant to Awards granted under this Policy.

8. SECTION 409A

In no event will cash compensation or expense reimbursement payments under this Policy be paid after the later of (i) the 15th day of the 3rd month following the end of the Company's fiscal year in which the compensation is earned or expenses are incurred, as applicable, or (ii) the 15th day of the 3rd month following the end of the calendar year in which the compensation is earned or expenses are incurred, as applicable, in compliance with the "short-term deferral" exception under Section 409A of the Internal Revenue Code of 1986, as amended, and the final regulations and guidance thereunder, as may be amended from time to time (together, "**Section 409A**"). It is the intent of this Policy that this Policy and all payments hereunder be exempt from or otherwise comply with the requirements of Section 409A so that none of the compensation to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be so exempt or comply. In no event will the Company reimburse an Outside Director for any taxes imposed or other costs incurred as a result of Section 409A.

9. REVISIONS

The Board may amend, alter, suspend or terminate this Policy at any time and for any reason. No amendment, alteration, suspension or termination of this Policy will materially impair the rights of an Outside Director with respect to compensation that already has been paid or awarded, unless otherwise mutually agreed between the Outside Director and the Company. Termination of this Policy will not affect the Board's or the Compensation Committee's ability to exercise the powers granted to it under the Plan with respect to Awards granted under the Plan pursuant to this Policy prior to the date of such termination.

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-3 (No. 333-249881) and Form S-8 (No. 333-234416) of Oyster Point Pharma, Inc. of our report dated February 18, 2021 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 18, 2021

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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 18, 2021

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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

ınt'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 18, 2021

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, 2020 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 18, 2021

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, 2020 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 18, 2021

By: /s/ Daniel Lochner
Daniel Lochner
Chief Financial Officer
(Principal Financial and Accounting Officer)