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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 1, 2020

Oyster Point Pharma, Inc.
(Exact name of Registrant as Specified in Charter)

Delaware	**001-39112**	**81-1030955**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

202 Carnegie Center, Suite 109 **Princeton, New Jersey** **(Address of Principal Executive Offices)**	**08540** **(Zip Code)**

(609) 382-9032
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 per share	**OYST**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

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

Item 8.01 Other Events.

Phase 2 Clinical Trial Protocol Submission Press Release

On December 1, 2020, Oyster Point Pharma, Inc. issued a press release announcing it has submitted to the U.S. Food and Drug Administration a Phase 2 clinical trial protocol to initiate a clinical study in adult patients with neurotrophic keratitis (NK), a degenerative disease characterized by decreased corneal sensitivity and poor corneal healing. The submission was made to Oyster Point's Investigational New Drug (IND) for OC-01 (varenicline) nasal spray in dry eye disease. Enrollment of the first patient in the Phase 2 study in NK is planned for the first half of 2021.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Oyster Point Pharma, Inc. dated December 1, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

OYSTER POINT PHARMA, INC.

Dated: December 2, 2020

By: /s/ Jeffrey Nau
Jeffrey Nau, Ph.D., M.M.S.
President and Chief Executive Officer

Oyster Point Pharma Submits a Phase 2 Clinical Trial Protocol to Evaluate OC-01 Nasal Spray for Neurotrophic Keratitis (NK)

Planned enrollment of the first patient in the OLYMPIA Phase 2 study in 1H 2021

PRINCETON, N.J. – Dec. 1, 2020 (GLOBE NEWSWIRE) – Oyster Point Pharma, Inc. (Nasdaq: OYST), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases, today announced it has submitted to the U.S. Food and Drug Administration (FDA) a protocol to initiate a clinical study in adult patients with neurotrophic keratitis (NK), a degenerative disease characterized by decreased corneal sensitivity and poor corneal healing. The submission was made to Oyster Point's Investigational New Drug (IND) for OC-01 (varenicline) nasal spray in dry eye disease. Enrollment of the first patient in the OLYMPIA Phase 2 study in NK is planned for the first half of 2021.

The OLYMPIA Phase 2 trial is a multi-center, randomized, double-masked, placebo-controlled study that will enroll adult subjects with NK. One-half of the adult subjects will receive one dose of OC-01 nasal spray twice daily for eight weeks; the other half will receive a placebo-controlled nasal spray. The study objective is to evaluate the safety and effectiveness of OC-01 nasal spray as compared to placebo for complete resolution of corneal staining in subjects with Stage 1 or Stage 2 NK in one or both eyes.

"Neurotrophic keratitis is the second of a number of important indications we are evaluating with OC-01 nasal spray, illustrating Oyster Point's commitment to treating unmet needs related to ocular surface diseases," said Jeffrey Nau, Ph.D., M.M.S., president and CEO of Oyster Point Pharma. "In pre-clinical and clinical studies, OC-01 has been shown to stimulate natural tear film, via a novel pathway found in the nasal mucosa, which allows the bypassing of corneal neuron stimulation of the tear film. We look forward to working with the FDA to advance this important study into the clinic."

In addition to NK, Oyster Point remains on track to file its new drug application (NDA) for OC-01 to treat the signs and symptoms of dry eye disease, a multifactorial condition of the ocular surface characterized by disruption of the tear film, in the fourth quarter of 2020.

About OC-01 Nasal Spray

OC-01 is a highly selective cholinergic agonist being developed as a preservative free nasal spray to treat the signs and symptoms of dry eye disease. The parasympathetic nervous system, the "rest and digest" system of the body, controls tear film homeostasis partially via the trigeminal nerve, which is accessible within the nose. Administered as a preservative-free, aqueous nasal spray, in pre-clinical and clinical studies OC-01 was shown to have a novel mechanism of action with activation of the trigeminal parasympathetic pathway in the nasal cavity to stimulate natural tear film production. Human tear film is a complex mixture of more than 1,500 different proteins, including growth factors and antibodies, as well as numerous classes of lipids and mucins. This complex tear film coating is responsible for forming the primary refracting surface of the cornea, as well as protecting and moisturizing the cornea. OC-01 nasal spray is an investigational new drug and has not been approved for any indication in any country. The safety and efficacy of OC-01 have not been established.

About Neurotrophic Keratitis

Neurotrophic keratitis (NK), also known as neuroparalytic keratitis or neurotrophic keratopathy, is a disease characterized by decreased corneal sensitivity and poor corneal healing. The most common causes of loss of corneal sensation are viral infection (herpes simplex and herpes zoster keratoconjunctivitis) followed by chemical burns, physical injuries, and corneal surgery. In addition, systemic diseases such as diabetes and

multiple sclerosis may decrease sensory nerve function or damage sensory fibers. NK can be classified broadly into three stages: Stage 1 (mild) consists of ocular surface irregularities and reduced vision, Stage 2 (moderate) exhibits a non-healing persistent defect of the corneal epithelium, and Stage 3 (severe) exhibits corneal ulceration, which may progress to corneal melting and perforation. If not adequately addressed, the progression of NK can lead to the loss of the cornea and the need for transplantation.

About Oyster Point Pharma, Inc.

Oyster Point Pharma is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases. Oyster Point Pharma's lead product candidate, OC-01 nasal spray, a highly selective cholinergic agonist, is being developed as a nasal spray to treat the signs and symptoms of dry eye disease. In pre-clinical and clinical studies, OC-01 nasal spray was shown to have a novel mechanism of action with activation of the trigeminal parasympathetic pathway to stimulate the glands and cells responsible for natural tear film production, known as the lacrimal functional unit.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions and on information currently available to us. The forward-looking statements in this press release represent our views as of the date of this press release. These statements may include but are not limited to statements regarding future events, including any potential impacts of any government measures in response thereto, or future financial and operating performance and our plans for and the anticipated benefits of new hires, our product candidates, the timing, objectives and results of the clinical studies and anticipated regulatory and development milestones, including potential timing of NDA submission and potential commercialization. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Important factors that could cause our actual results to differ materially are detailed from time to time in the "Risk Factors" section in reports we file with the Securities and Exchange Commission, copies of which are posted on our website and are available from us without charge. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties.

Investor Contact
Tim McCarthy
LifeSci Advisors, LLC
(212) 915-2564
investors@oysterpointrx.com

Media Contact:
Sheryl Seapy, W2O Group
(213) 262-9390
sseapy@w2ogroup.com

# # #