**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)**

**November 4, 2021**

# Oyster Point Pharma, Inc.

**(Exact name of registrant as specified in its charter)**

| Delaware | 001-36002 | 81-1030955 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**202 Carnegie Center, Suite 109**
**Princeton, New Jersey 08540**
**(Address, including zip code, of Registrant's principal executive offices)**

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

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 (see General Instruction A.2. below):

☐ 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 2.02 Results of Operations and Financial Condition.**

On November 4, 2021, Oyster Point Pharma, Inc. (the "Company") issued a press release to report the Company's financial results for the quarter ended September 30, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 and the attached Exhibit 99.1 are being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed to be incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 2.04 Triggering Events That Accelerate or Increase a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement**

As previously announced, on August 5, 2021, the Company entered into a $125 million term loan credit facility, as amended on October 19 (the "Credit Agreement") with OrbiMed Royalty & Credit Opportunities III, LP, as administrative agent and initial lender ("OrbiMed"). The Company delivered a notice to OrbiMed that it intended to borrow the second $50 million tranche under the Credit Agreement on October 19, 2021, and the Company received the second tranche of funding under the Credit Agreement from OrbiMed on November 4, 2021.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated November 4, 2021 |
| 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.**

Date: November 4, 2021

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

# Oyster Point Pharma Reports Third Quarter 2021 Financial Results and Recent Business Highlights

- **FDA Approval of TYRVAYA ™ (varenicline solution) Nasal Spray for the Treatment of the Signs and Symptoms of Dry Eye Disease on October 15, 2021**
- **Field Force Onboarding Completed During Q3'21, U.S. Launch of TYRVAYA Nasal Spray Initiated on Nov. 1st. TYRVAYA is Now Available at U.S. Regional Wholesalers for Distribution to Pharmacies**
- **$17.9 Million in Revenue Recognized from Ji Xing Pharmaceuticals (Ji Xing) During Q3'21**
- **Following FDA Approval of TYRVAYA Nasal Spray on October 15th Company Received $5 Million Development Milestone Payment and the Remaining Senior Common Shares in Ji Xing**
- **Waiver and Amendment to the OrbiMed Credit Agreement and Exercise of Option to Borrow the Second $50 Million Tranche; Second Tranche Received on November 4th**
- **Conference Call and Webcast Scheduled for 4:30 pm ET Today**

**PRINCETON, N.J.,** November 4, 2021 (GLOBE NEWSWIRE) — Oyster Point Pharma, Inc. (Nasdaq: OYST), ("Oyster Point Pharma" or "the Company") a commercial-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ophthalmic diseases, today announced its financial results for the third quarter of 2021, and provided an overview of recent business highlights.

“Oyster Point Pharma has achieved significant milestones recently, including the onboarding of our talented field force and the U.S. Food and Drug Administration (FDA) approval of TYRVAYA™ (varenicline solution) Nasal Spray. In addition, we are excited to announce that, as of Monday, November 1st, our field force has commenced the launch of TYRVAYA™ Nasal Spray for patients and the eye care practitioners who care for them.” said Jeffrey Nau, Ph.D., MMS, president and chief executive officer of Oyster Point Pharma. Dr. Nau continued, "With our launch of TYRVAYA Nasal Spray underway, we look forward to helping patients with dry eye disease as well as continuing our mission to develop novel therapeutic treatments for ophthalmic diseases.”

**Recent Business Highlights**

- **FDA Approval of TYRVAYA ™ (varenicline solution) Nasal Spray for the Treatment of the Signs and Symptoms of Dry Eye Disease.** On October 15, 2021, the FDA approved TYRVAYA Nasal Spray for the treatment of the signs and symptoms of dry eye disease. TYRVAYA Nasal Spray’s differentiated mechanism of action is believed to activate the trigeminal parasympathetic pathway resulting in increased production of basal tear film as a treatment for dry eye disease. The exact mechanism of action is unknown at this time.

- **Field Force Onboarding Completed During Q3’21, U.S. Launch of TYRVAYA Nasal Spray Initiated on November 1, 2021**. The Company completed the onboarding of its planned field force of 150-200 field-based sales resources during the third quarter, who have been communicating the Company's dry eye disease-state awareness campaign. As of November 1st, the field force has initiated calling on Eye Care Practitioners to market TYRVAYA Nasal Spray. TYRVAYA Nasal Spray is now available at U.S. regional wholesalers for distribution to pharmacies, and samples are available to Eye Care Practitioners.

- **$17.9 Million in Revenue Recognized from Ji Xing Pharmaceuticals License and Collaboration Agreement During Q3’21**. The Company recognized $17.9 million in revenue in connection with the Ji Xing License and Collaboration Agreement in Q3’21, which includes the partial, non-cash consideration of Ji Xing senior common shares. Following FDA approval of TYRVAYA Nasal Spray on October 15, 2021, the Company received an additional $5 million development milestone payment and the remaining senior common shares in Ji Xing.

- **Waiver and Amendment to the OrbiMed Royalty & Credit Opportunities III, LP (OrbiMed) Credit Agreement and Exercise of Option to Borrow Second $50 Million Tranche; Second Tranche Received on November 4th.** On October 19, 2021, the Company entered into a waiver and amendment to the August 2021 Credit Agreement with OrbiMed to waive certain labeling requirements required to permit the availability of the

second, $50 million tranche of funding under the Credit Agreement, among other revisions. The Company issued a borrowing notice to OrbiMed for the second tranche and received the second tranche funds on November 4, 2021.

**Overview of Financial and Operating Results**

**Third Quarter 2021 Financial Results**

- **Cash Position:** As of September 30, 2021, cash and cash equivalents were $184.2 million, compared to $192.6 million as of December 31, 2020.

- **License Revenue - Related Party:** In connection with the license agreement with Ji Xing, the Company recognized $17.9 million in license revenue during the three months ended September 30 2021, which is inclusive of the partial, non-cash consideration of Ji Xing senior common shares. Of this amount, the Company received $15.0 million in cash consideration during the three months ended September 30, 2021 and $2.5 million is included in other receivables – related party as of September 30, 2021.

- **R&D Expenses:** Research and development expenses decreased by $2.0 million during the three months ended September 30, 2021 compared to the three months ended September 30, 2020. The decrease was primarily driven by lower chemistry, manufacturing and controls (CMC) expenses incurred by the Company in the third quarter of 2021 compared to the third quarter of 2020, which included significant pre-approval inventory costs, as well as expenses related to the preparation of the NDA filing in December 2020. The Company also incurred lower clinical and pre-clinical expense due to the timing and number of the studies conducted during the three months ended September 30, 2021 compared to the three months ended September 30, 2020.

- **SG&A Expenses:** Selling, general and administrative expenses increased by $20.4 million during the three months ended September 30, 2021 compared to the three months ended September 30, 2020. The increase was driven by higher payroll-related expenses of $11.2 million, inclusive of increase in stock-based compensation of $0.8 million, primarily driven by onboarding a commercial field force during the three months ended September 30, 2021. In addition, the Company incurred higher commercial planning expenses of $5.2 million in anticipation of a U.S. launch of TYRVAYA Nasal Spray, and higher general and administrative expenses of $3.1 million, related to accounting, legal, facilities, and information technology costs. The Company also incurred higher medical affairs costs in the amount of $0.9 million during the three months ended September 30, 2021 compared to the three months ended September 30, 2020.

- **Interest Expense:** The Company incurred $1.1 million of interest expense during the three months ended September 30, 2021, related to the term loan credit facility entered into in August 2021.

- **Net Loss:** For the third quarter of 2021, the Company had a net loss of $17.7 million, or $(0.68) per share, compared to a net loss of $16.3 million, or $(0.63) per share, for the same period in 2020.

Oyster Point Pharma will host a live conference call and webcast today at 4:30 pm Eastern Time to discuss the third quarter 2021 financial results and provide a business update. To access the live call by phone, please dial (855) 548-1220 (US/Canada) or (602) 563-8619 (International). The conference ID number is 4538958. The webcast will be made available at https://edge.media-server.com/mmc/p/z323rvd3 on the company's website at www.oysterpointrx.com under the "Events & Presentations" section .

A telephone replay will be available for approximately 7 days following the live conference call. To access the telephone replay, please dial (855) 859-2056 (US/Canada) or (404) 537-3406 (International). The conference ID number is 4538958.

**About Oyster Point Pharma, Inc.**
Oyster Point Pharma is a commercial-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ophthalmic diseases. In October 2021, Oyster Point Pharma received FDA-approval for TYRVAYA™ (varenicline solution) Nasal Spray for the treatment of the signs and symptoms of dry eye disease. Oyster Point has a growing pipeline of clinical and pre-clinical

programs and continues to expand its research and development pipeline through internal innovation and external collaborations. Oyster Point is continuously striving to advance breakthrough science and deliver therapies seeking to address the unmet needs of patients with ophthalmic disease and the eye care professionals who take care of them. For more information, visit www.oysterpointrx.com and follow @OysterPointRx on Twitter and LinkedIn.

**About TYRVAYA™ (varenicline solution) Nasal Spray**
TYRVAYA (varenicline solution) Nasal Spray 0.03 mg (formerly referred to as OC-01) is a highly selective cholinergic agonist that is FDA-approved to treat the signs and symptoms of dry eye disease as a multidose nasal spray. 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. The efficacy of TYRVAYA Nasal Spray in dry eye disease is believed to be the result of varenicline's activity at heteromeric sub-type(s) of the nicotinic acetylcholine (nACh) receptor where its binding produces agonist activity and activates the trigeminal parasympathetic pathway resulting in increased production of basal tear film as a treatment for dry eye disease. Varenicline binds with high affinity and selectivity at human α4β2, α4α6β2, α3β4, α3α5β4 and α7 neuronal nicotinic acetylcholine receptors. The exact mechanism of action is unknown at this time.

**About Dry Eye Disease and the Role of Tear Film**
Dry eye disease is a chronic condition that impacts an estimated 38 million people in the U.S. and is growing in prevalence1,2. It can cause persistent stinging, scratching, burning sensations, sensitivity to light, blurred vision, and eye fatigue. Dry eye disease is a multifactorial disease of the ocular surface characterized by disruption of the tear film. 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 mucins3. Natural tear film protects and lubricates the eyes, washes away foreign particles, contains growth factors and antimicrobial components, and creates a smooth surface that forms the primary refractive surface of the eye.

**Forward-Looking Statements**
This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 that reflect the current beliefs, expectations and assumptions of Oyster Point Pharma, Inc. (the “Company,” “we” or “our”) regarding the future of the Company’s business, our future plans and strategies, regulatory approvals, preclinical and clinical results, future financial condition and other future conditions. All statements other than statements of historical facts contained in this press release, including express or implied statements regarding future results of operations and financial position, business strategy, product candidates, regulatory approvals, expected research and development costs, planned preclinical studies and clinical trials, expected results of preclinical studies or clinical trials, and their timing and likelihood of success, expected research and development costs, as well as plans and objectives of management for future operations, are forward-looking statements. The words "if approved," “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 are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: our plans and potential for success relating to commercializing TYRVAYA; the beneficial characteristics, safety, efficacy and therapeutic effects of TYRVAYA and our preclinical and clinical product candidates; our plans relating to the further development and manufacturing of TYRVAYA and our preclinical and clinical candidates, including potential additional indications or disease areas to be evaluated and pursued; the timing of initiation of our future preclinical studies or clinical trials; the uncertainties inherent in pharmaceutical research and development, including preclinical study and clinical trial results and additional analysis of existing data; the likelihood of clinical trials demonstrating safety and efficacy of our product candidates, and other positive results; the timing or likelihood of regulatory filings and approvals of TYRVAYA and our clinical and preclinical candidates, including in potential additional indications for TYRVAYA and potential filings in additional jurisdictions; the prevalence of dry eye disease and Neurotrophic Keratopathy (NK) and the size of the market opportunities for our product candidates; the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise; existing regulations and regulatory developments in the United States and other jurisdictions; our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available; our continued reliance on third parties to conduct additional preclinical studies and clinical trials of our product candidates, and for the manufacture of our product

candidates for preclinical studies and clinical trials, and potentially for commercial supply; our ability to recruit and retain key personnel needed to develop and commercialize our product candidates, if approved, and to grow our company; the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; our financial performance; market conditions; the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements; our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and other risks described in the “Risk Factors” section included in our public filings that we have made and will make with the Securities and Exchange Commission (SEC).

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**Oyster Point Pharma, Inc.**
**Select Balance Sheet Data**
(in thousands)
(unaudited)

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Cash and cash equivalents | $ 184,166 | $ 192,585 |
| Working capital* | $ 174,525 | $ 185,385 |
| Total assets | $ 195,009 | $ 197,910 |
| Stockholders' equity | $ 137,512 | $ 186,659 |

*Working capital is defined as current assets less current liabilities.

**Oyster Point Pharma, Inc.**
**Statements of Operations and Comprehensive Loss**
(in thousands, except share and per share amounts)
(unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| **Revenue:** | | | | |
| License revenue - related party | $ 17,943 | $ — | $ 17,943 | $ — |
| Total revenue | 17,943 | — | 17,943 | — |
| **Research and development:** | | | | |
| Clinical, preclinical | 1,467 | 2,148 | 5,468 | 10,141 |
| Chemistry, manufacturing and controls | 3,727 | 4,676 | 12,772 | 14,236 |
| Other | 1,020 | 1,386 | 532 | 3,727 |
| Total research and development | 6,214 | 8,210 | 18,772 | 28,104 |
| **Selling, general and administrative** | 28,497 | 8,112 | 56,885 | 20,641 |
| Loss from operations | (16,768) | (16,322) | (57,714) | (48,745) |
| **Other income (expense)** | | | | |
| Other income, net | 222 | 17 | 243 | 457 |
| Interest expense | (1,124) | — | (1,124) | — |
| Total other expense, net | (902) | 17 | (881) | 457 |
| **Net loss and comprehensive loss** | (17,670) | (16,305) | (58,595) | (48,288) |
| **Net loss per share, basic and diluted** | $ (0.68) | $ (0.63) | $ (2.25) | $ (2.05) |
| **Weighted average shares outstanding, basic and diluted** | 26,037,975 | 25,797,282 | 25,984,412 | 23,544,035 |