



Oyster Point Pharma Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Business Highlights

February 24, 2022

- **FDA Approved TYRVAYA™ (varenicline solution) Nasal Spray for the Treatment of the Signs and Symptoms of Dry Eye Disease on October 15, 2021**
- **TYRVAYA Nasal Spray Net Product Revenue of \$1.2 Million in Q4'21, plus \$5.4 Million Recognized from Ji Xing Pharmaceuticals (Ji Xing) License Agreement in Q4'21**
- **Over 5,500 TYRVAYA Prescriptions Filled; Prescriptions Written by Approximately 1,900 Unique Eye Care Professionals in November and December 2021**
- **\$50 Million Drawn on Second Tranche from OrbiMed Royalty & Credit Opportunities III, LP (OrbiMed), Cash Received on November 4, 2021**
- **Continue to Enroll OLYMPIA Phase 2 Clinical Trial, Study Results Expected in 2H 2022**
- **Conference Call and Webcast Scheduled for 4:30 pm ET Today**

PRINCETON, N.J., Feb. 24, 2022 (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 fourth quarter and full year ended December 31, 2021 and provided an overview of recent business highlights.

"We are proud of what we achieved in 2021, including the launch of TYRVAYA™ (varenicline solution) Nasal Spray, an exclusive license agreement to develop and commercialize OC-01 and OC-02 in Greater China, securing non-dilutive funding, a strategic research collaboration, and meaningful R&D progress," said Jeffrey Nau, Ph.D., MMS, president and chief executive officer of Oyster Point Pharma. "In 2022, Oyster Point Pharma remains committed to successful commercial execution of TYRVAYA Nasal Spray and exploring new areas of science in ophthalmology and determined to bring forth scientific breakthroughs on behalf of patients with unmet needs."

Recent Business Highlights

- **FDA Approved TYRVAYA (varenicline solution) Nasal Spray for the Treatment of the Signs and Symptoms of Dry Eye Disease:** On October 15, 2021, the U.S. Food and Drug Administration (FDA) approved TYRVAYA Nasal Spray for the treatment of the signs and symptoms of dry eye disease. On November 3, 2021, TYRVAYA became available at U.S. regional wholesalers for distribution to pharmacies and for home delivery. TYRVAYA is believed to activate the trigeminal parasympathetic pathway, resulting in increased basal tear film production as a treatment for dry eye disease. Over 5,500 total prescriptions for TYRVAYA were filled in November and December and were written by approximately 1,900 unique Eye Care Professionals. This demonstrates early adoption of the first and only nasal spray approved for the treatment of the signs and symptoms of dry eye disease and indicates strong momentum heading into 2022.
- **TYRVAYA Net Product Revenue of \$1.2 Million and \$5.4 Million in Revenue Recognized from the Ji Xing License Agreement in Q4'21:** In Q4'21, the Company recognized \$1.2 million of net product revenue related to sales of TYRVAYA Nasal Spray, which was launched in November 2021. Approximately half of the TYRVAYA net product revenue was attributable to channel building by distributors upon launch of the product. The Company also recognized \$5 million in milestone revenue, plus an additional \$0.4 million in license revenue for the remaining, non-cash consideration of Ji Xing senior common shares, in connection with the Ji Xing License Agreement.
- **Draw on \$50 Million Second Tranche from OrbiMed, Cash Received on November 4th:** On November 4, 2021, the Company drew on the \$50 million second tranche in connection with the OrbiMed Credit Agreement. At the option of the Company, the remaining \$30 million third tranche may be funded on or prior to June 30, 2023, upon the Company having received at least \$40 million in TYRVAYA Nasal Spray net recurring revenue, as defined in the Credit Agreement, in any twelve-month period prior to March 31, 2023, among other conditions.
- **Continue Enrollment of Subjects in the OLYMPIA Phase 2 Clinical Trial of OC-01 (varenicline) Nasal Spray for Patients with Stage 1 Neurotrophic Keratopathy (NK):** In June 2021, the Company announced enrollment of the first subject in the OLYMPIA Phase 2 clinical trial of OC-01 (varenicline) nasal spray for the treatment of Stage 1 Neurotrophic Keratopathy (NK). Enrollment is expected to continue through the first half of 2022 with results expected in the second half of 2022.

- **Meaningful Progress for Two Pre-clinical Studies, Enriched Tear Film (ETF™) Gene Therapy, Bacteriophage Collaboration:** The Company has continued to progress a number of pre-clinical studies and anticipates holding pre-IND meetings with the FDA in the first half of 2022 to discuss next steps for OC-101 (AAV-NGF), a single, intralacrima gland injection of an AAV containing the human NGF (nerve growth factor) gene for Stage 2/3 Neurotrophic Keratopathy patients, and for the OC-300 bacteriophage program.

Overview of Financial and Operating Results

Fourth Quarter 2021 Financial Results

- **Cash Position:** As of December 31, 2021, cash, cash equivalents, and restricted cash were \$193.4 million, compared to \$184.2 million as of September 30, 2021. The increase in cash, cash equivalents, and restricted cash during the three months ended December 31, 2021 in the amount of \$9.2 million was mainly due to cash provided by financing operations in the amount of \$50.9 million, primarily due to borrowing under the OrbiMed Credit Agreement and to a lesser extent proceeds from the exercise of stock options, partially offset by cash used in operations in the amount of \$41.5 million and capital expenditures in the amount of \$0.2 million.
- **Product Revenues, Net:** Net product revenues for the three months ended December 31, 2021 were \$1.2 million following the approval of TYRVAYA Nasal Spray by the FDA on October 15, 2021, and its subsequent commercial launch in the U.S. in November 2021. The Company did not generate any revenues from product sales during the three months ended December 31, 2020.
- **Milestone and License Revenue:** Pursuant to the license agreement with Ji Xing, a related party, the Company recognized \$5.4 million in milestone and license revenue upon the FDA approval of TYRVAYA Nasal Spray, which includes the non-cash consideration of the remaining Ji Xing senior common shares. The Company had no milestone or license revenue during the three months ended December 31, 2020.
- **Cost of Product Revenue:** Cost of product revenue for the three months ended December 31, 2021 was \$1.5 million and mainly consisted of third-party manufacturing costs including pre-approval costs, reserves for inventory obsolescence and damaged goods, and product royalty expenses. The cost of product revenue includes a reserve for inventory obsolescence of \$0.9 million. Inventory manufactured prior to FDA approval was charged to research and development expense, and as such the unit cost of product revenue will be lower until the Company fully utilizes product manufactured prior to the FDA approval date of TYRVAYA Nasal Spray. The Company started expensing the pre-approval inventory in 2020 and recorded approximately \$4.3 million as research and development expense related to such pre-approval inventory during the year ended December 31, 2021. The Company anticipates selling the remaining pre-approval inventory by the end of 2022.
- **Sales and Marketing Expenses:** The Company's sales and marketing expenses increased by \$21.8 million during the three months ended December 31, 2021, compared to the same period in 2020. The increase was primarily due to higher payroll-related expenses of \$11.7 million, inclusive of sales commission expense, as well as an increase in stock-based compensation expense of \$0.5 million, both of which were primarily driven by onboarding a commercial field force in the second half of 2021. The Company also incurred higher marketing, market access, commercial and other expenses of \$10.1 million in anticipation of, and in connection with the U.S. launch of TYRVAYA Nasal Spray.
- **General and Administrative Expenses:** The Company's general and administrative expenses increased by \$6.2 million during the three months ended December 31, 2021, compared to the same period in 2020. The increase was primarily due to higher general and administrative expenses of \$3.8 million related to accounting, consulting, legal and other professional expenses incurred in connection with the Credit Agreement, as well as the Company's transition from a clinical-stage to a commercial-stage company. The Company also incurred higher payroll-related expenses of \$2.4 million, including recruiting expense, due to an increase in headcount to support its ongoing efforts to commercialize TYRVAYA.
- **Research and Development Expenses:** The Company's research and development expenses decreased by \$6.2 million during the three months ended December 31, 2021, compared to the same period in 2020. The Company's decrease in research and development expense was primarily due to the Company receiving FDA approval of TYRVAYA Nasal Spray in October 2021. The Company expensed inventory prior to receiving FDA approval and expensed approximately \$3.5 million as research and development during the three months ended December 31, 2020. The Company also incurred a fee of \$2.9 million in connection with the new drug application submitted to the FDA in December 2020. The expense was subsequently reversed in the first quarter of 2021 as the Company was granted a waiver and refund of the fee.
- **Interest expense:** The Company incurred interest expense of \$2.6 million during the three months ended December 31, 2021, primarily related to the Credit Agreement with OrbiMed. Interest expense included contractual interest of \$1.7 million, as well as non-cash expense of \$0.9 million related to amortization of loan commitment fees and accretion of other

long-term debt related costs. The Company had no interest expense during the three months ended December 31, 2020.

- **Net Loss:** For the three months ended December 31, 2021, the Company had a net loss of \$42.1 million, or \$1.61 per share, compared to a net loss of \$22.2 million, or \$0.86 per share, for the three months ended December 31, 2020.

Conference Call Details and Webcast

Oyster Point Pharma will host a live conference call and webcast today at 4:30 pm Eastern Time to discuss the fourth 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 7788145. The webcast will be made available [here](#) 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 7788145.

About Oyster Point Pharma

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 [Twitter](#) and [LinkedIn](#).

About TYRVAYA™(varenicline solution) Nasal Spray

TYRVAYA (varenicline solution) Nasal Spray 0.03 mg 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 $\alpha 4\beta 2$, $\alpha 4\alpha 6\beta 2$, $\alpha 3\beta 4$, $\alpha 3\alpha 5\beta 4$ and $\alpha 7$ neuronal nicotinic acetylcholine receptors. The exact mechanism of action is unknown at this time.

TYRVAYA™Important Safety Information

The most common adverse reaction reported in 82% of patients was sneezing. Events that were reported in 5- 16% of patients were cough, throat irritation, and instillation-site (nose) irritation. There are no contraindications associated with TYRVAYA™ (varenicline solution) Nasal Spray. Please see full Prescribing Information at www.tyrvaya-pro.com/prescribinginformation.

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 prevalence.^{1,2} 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 mucins.³ 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, commercial opportunities, 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, commercialization efforts, product candidates, regulatory approvals, expected research and development costs, 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 the likelihood of positive preclinical study results, and the likelihood of clinical trials demonstrating the safety and efficacy of our product or product candidates; 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 and product candidates; our ability to recruit and retain key

personnel needed to develop and commercialize our product and product candidates, 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).

References:

1. Wirta, D., Vollmer, P., Paauw, J., Chiu, K. H., Henry, E., Striffler, K., ... & ONSET-2 Study Group. (2021). Efficacy and Safety of OC-01 (Varenicline) Nasal Spray on Signs and Symptoms of Dry Eye Disease: the ONSET-2 Phase 3, Randomized Trial. *Ophthalmology*. <https://doi.org/10.1016/j.ophtha.2021.11.004>
2. Market-Scope. 2020 Dry Eye Products Report: A Global Market Analysis for 2019 to 2025. October 2020.
3. Tsubota K, Pflugfelder S, Liu Z, Baudouin C. Defining dry eye from a clinical perspective. *Int J Mol Sci*. 2020;21(23):1-24. <https://pubmed.ncbi.nlm.nih.gov/33291796/>

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Oyster Point Pharma, Inc.

Select Balance Sheet Data

(in thousands)

	December 31, 2021		December 31, 2020	
Cash and cash equivalents	\$	193,372	\$	192,585
Working capital*	\$	186,448	\$	185,385
Total assets	\$	222,617	\$	197,910
Long-term debt	\$	89,815	\$	-
Stockholders' equity	\$	99,537	\$	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)

	Three months ended December 31,		Year ended December 31,	
	2021	2020	2021	2020
	<i>(unaudited)</i>			
Revenue:				
Product revenue, net	1,153	-	1,153	-
Milestone revenue - related party	5,000	-	5,000	-
License revenue - related party	443	-	18,386	-
Total revenue	\$ 6,596	\$ -	\$ 24,539	\$ -
Cost of product revenue	\$ 1,525	\$ -	\$ 1,525	\$ -
Operating expenses:				
Sales and marketing	25,675	3,864	54,622	9,873
General and administrative	12,875	6,673	40,813	21,305
Research and development	5,462	11,707	24,234	39,811
Total operating expenses	\$ 44,012	\$ 22,244	\$ 119,669	\$ 70,989
Loss from operations	\$ (38,941)	\$ (22,244)	\$ (96,655)	\$ (70,989)
Other income (expense):				
Interest expense	(2,610)	-	(3,734)	-
Other income, net	(513)	12	(270)	469
Total other income (expense), net	(3,123)	12	(4,004)	469

Net loss and comprehensive loss	\$ (42,064)	\$ (22,232)	\$ (100,659)	\$ (70,520)
Net loss per share, basic and diluted	\$ (1.61)	\$ (0.86)	\$ (3.87)	\$ 2.92
Weighted average shares outstanding, basic and diluted	<u>26,191,210</u>	<u>25,869,601</u>	<u>26,036,536</u>	<u>24,128,603</u>