Oyster Point Pharma Reports First Quarter 2022 Financial Results and Recent Business Highlights

May 5, 2022

- **TYRVAYA® Nasal Spray Net Product Revenue of $2.7 Million in Q1'22**
- **Approximately 19,000 TYRVAYA Prescriptions Filled During the Quarter, with Prescriptions Written by Over 4,500 Unique Eye Care Professionals**
- **Expansion of Commercial Coverage for TYRVAYA, with Up to Approximately 95 Million Lives Covered to Date**
- **Licensing Partner, Ji Xing Pharmaceuticals, Authorized to Conduct Phase 3 Clinical Trial of OC-01 in China**
- **Continuing Enrollment of Subjects in the OLYMPIA Phase 2 Clinical Trial for Stage 1 Neurotrophic Keratopathy, with Study Results Expected in 2H 2022**
- **Additional Pre-Clinical Studies Underway for Enriched Tear Film Gene Therapy to Target Stages 2 and 3 Neurotrophic Keratopathy**
- **Conference Call and Webcast Scheduled for 4:30 pm ET Today**

PRINCETON, N.J., May 05, 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 quarter ended March 31, 2022, and provided an overview of recent business highlights.

"We are very pleased with the performance of Oyster Point Pharma's first full quarter since the launch of TYRVAYA®." said Jeffrey Nau, Ph.D., MMS, president and chief executive officer of Oyster Point Pharma. "With approximately 19,000 TYRVAYA prescriptions written during the quarter as well as expanded patient access and positive feedback from eye care professionals and patients, we are well poised for accelerated growth. We're entering the remainder of 2022 with strong momentum, progressing our exciting pipeline assets and remaining focused on bringing transformational eye care therapies to patients while creating long-term value for our shareholders."

Recent Business Highlights

- **TYRVAYA® (varenicline solution) Nasal Spray Net Product Revenue of $2.7 Million in Q1'22 with Approximately 19,000 Prescriptions Filled:** In Q1'22, the Company recognized $2.7 million of net product revenue related to sales of TYRVAYA Nasal Spray, which was launched in November 2021. Approximately 19,000 TYRVAYA prescriptions were filled during the first quarter of 2022. Prescriptions were written by over 4,500 unique eye care professionals during the quarter, demonstrating continued strong momentum for the adoption of TYRVAYA as the first and only nasal spray approved for the treatment of the signs and symptoms of dry eye disease.
- **Expansion of Commercial Coverage for TYRVAYA:** Effective February 19, 2022, TYRVAYA was placed on the Express Scripts National Preferred, Basic, and High Performance Formularies, which collectively make up an estimated 26 million lives. Subsequently, formulary coverage for TYRVAYA has been established with additional payors. According to a third-party syndicated source, TYRVAYA now has commercial coverage for up to approximately 95 million lives, or 52% of all U.S. commercial lives. The Company anticipates receiving coverage determinations for all major commercial payors in the U.S. by mid-2022.
- **Licensing Partner, Ji Xing Pharmaceuticals, Authorized to Conduct Phase 3 Clinical Trial of OC-01 in China:** On March 21, 2022, Ji Xing Pharmaceuticals, a licensing partner of the Company, announced authorization to conduct a phase 3 clinical trial of OC-01 (varenicline tartrate) nasal spray for the treatment of the signs and symptoms of dry eye disease in Greater China. In addition to the collaboration and license agreement with Ji Xing Pharmaceuticals, the Company may continue to seek additional international partners with capabilities and infrastructure in other geographies to potentially further clinical development and commercialization of OC-01 (varenicline) or OC-02 (simpinicline) or the Company's other product candidates outside of the U.S.

Upcoming Milestones

- **Continued Enrollment of Subjects in the OLYMPIA Phase 2 Clinical Trial for Stage 1 Neurotrophic Keratopathy (NK):** In Q1'22, the Company continued to enroll patients in the OLYMPIA Phase 2 clinical trial of OC-01 (varenicline) nasal spray for the treatment of Stage 1 NK. Enrollment will continue with results expected in the second half of 2022.
- **Additional Pre-Clinical Studies Underway for Enriched Tear Film (ETF™) Gene Therapy to Target Stages 2 and 3 NK:** In Q1'22, the Company progressed its multiple pre-clinical studies for OC-101 (AAV-NGF), a single, intralacrimal gland injection of an adeno-associated virus (AAV) vector containing the human nerve growth factor (NGF) gene for Stages 2 and 3 NK patients. Additional pre-clinical studies using a porcine model have further demonstrated the capability of ETF Gene Therapy to deliver a protein to the tear film following intralacrimal gland injection. The Company anticipates holding

pre-IND meetings with the FDA in the second half of 2022 to discuss next steps for OC-101 (AAV-NGF).

Overview of Financial and Operating Results

First Quarter 2022 Financial Results

- **Cash Position:** As of March 31, 2022, cash and cash equivalents was $143.4 million, compared to $193.4 million as of December 31, 2021. The decrease in cash and cash equivalents during the three months ended March 31, 2022, of $50.0 million was primarily used to fund operating activities incurred to market TYRVAYA Nasal Spray.
- **Product Revenues, Net:** Net product revenues for the three months ended March 31, 2022, were $2.7 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 March 31, 2021.
- **Cost of Product Revenue:** Cost of product revenue for the three months ended March 31, 2022, was $0.3 million and consisted of product royalty expenses, third-party manufacturing costs, reserves for inventory obsolescence and material costs of $0.7 million. This was partially offset by the $0.4 million supplier credit recognized during the three months ended March 31, 2022. In preparation of the commercial launch, the Company expensed to research and development expense all material costs related to inventory produced prior to the October 15, 2021, FDA approval date of TYRVAYA Nasal Spray (pre-approval inventory). Because pre-approval inventory was charged to research and development expense, the unit cost of product revenue will be lower until the Company fully utilizes the pre-approval inventory.
- **Sales and Marketing Expenses:** Sales and marketing expenses for the three months ended March 31, 2022, were $27.0 million, an increase of $22.4 million compared to the same period in 2021. The increase was primarily due to higher payroll-related expenses of $11.6 million, inclusive of an increase in stock-based compensation of $0.7 million, as well as sales commission expense, which was primarily driven by onboarding a commercial field force in the second half of 2021. The Company also incurred higher marketing expenses of $8.5 million in connection with advertising, sample expense, trade shows, and other marketing efforts related to the launch of TYRVAYA Nasal Spray.
- **General and Administrative Expenses:** General and administrative expenses for the three months ended March 31, 2022, were $12.9 million, an increase of $4.4 million compared to the same period in 2021. The increase was primarily driven by additional payroll-related expenses of $2.6 million due to an increase in headcount to support the Company's business operations, inclusive of an increase in stock-based compensation of $0.7 million. The Company also incurred higher other general and administrative expenses of $1.3 million related to accounting, legal and other professional services, and insurance. The increase in other general and administrative expense was driven by the Company's transition from a clinical stage to a commercial stage company.
- **Research and Development Expenses:** Research and development expenses for the three months ended March 31, 2022, were $4.7 million, a decrease of $1.1 million compared to the same period in 2021. The decrease was primarily due to decreased research and development activity relating to OC-01 following its approval by the FDA on October 15, 2021.
- **Interest Expense:** The Company incurred interest expense of $3.1 million during the three months ended March 31, 2022, related to the Company's credit agreement with OrbiMed entered into in August 2021. Interest expense for the three months ended March 31, 2022, included contractual interest, as well as the 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 March 31, 2021.
- **Net Loss:** For the three months ended March 31, 2022, the Company had a net loss of $47.9 million, or ($1.80) per share, compared to a net loss of $18.9 million, or ($0.73) per share, for the three months ended March 31, 2021.

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 first quarter 2022 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 4149318. The webcast will be made available here and 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 4149318.

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 Pharma 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 Pharma 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 α4β2, α4α6β2, α3β4, α3α5β4 and α7 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, as amended, including, without limitation, implied and express statements regarding the future of the Company's business, the Company's future plans and strategies, commercial opportunities, interactions with regulators, regulatory approvals, preclinical and clinical results, future financial condition, the timing of preclinical and clinical trials, including data from such trials and other expected milestones, the timing of coverage determinations for TYRVAYA Nasal Spray and the potential therapeutic and clinical benefits of the Company’s product candidates and other future conditions. The words "if approved," “may,” “will,” “should,” “would,” “expect,” “plan,” “pipeline,” “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. The reader is cautioned not to rely on these forward-looking statements. All forward-looking statements contained in this press release are based on current expectations and assumptions of the Company, and are subject to a number of risks, uncertainties and assumptions, including, among other things: the Company’s plans and potential for success relating to commercializing TYRVAYA; the beneficial characteristics, safety, efficacy and therapeutic effects of TYRVAYA and the Company’s preclinical and clinical product candidates; the Company’s plans relating to the further development and manufacturing of TYRVAYA and its preclinical and clinical candidates, including potential additional indications or disease areas to be evaluated and pursued; the timing of initiation of the Company’s 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 the Company’s 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 the Company’s product candidates; 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 throughout the world, including extensions of existing patent terms where available; the Company’s continued reliance on third parties to conduct additional preclinical studies and clinical trials of its product candidates, and for the manufacture of its product and product candidates; economic factors, such as interest rate and currency exchange rate fluctuations; manufacturing difficulties or delays, internally or within the supply chain; product efficacy or safety concerns resulting in product recalls or regulatory action; financial instability of international economies and legal systems and sovereign risk; risks related to the impact of the COVID-19 global pandemic, such as the scope and duration of the outbreak, government actions and restrictive measures implemented in response, material delays and cancellations of medical procedures, supply chain disruptions and other impacts to the business, or on the Company’s ability to execute business continuity plans, as a result of the COVID-19 pandemic; the Company’s ability to recruit and retain key personnel needed to develop and commercialize its product and product candidates, and to grow the Company; the accuracy of the Company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing; the Company's financial performance; market conditions; the sufficiency of the Company's existing capital resources to fund its future operating expenses and capital expenditure requirements; and the Company’s expectations regarding the period during which it will qualify as an emerging growth company under the JOBS Act. A further list and descriptions of these risks, uncertainties and other factors can be found in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2021, including in the sections captioned “Special Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in the Company’s subsequent Quarterly Reports on Form 10-Q and other filings that it makes with the Securities and Exchange Commission from time to time. Copies of these filings are available online at www.oysterpointrx.com. Any forward-looking statement made in this press release speaks only as of the date of this release. The Company does not undertake to update any forward-looking statement as a result of new information or future events or developments, except as required by law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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/

Investor Contact
Arty Ahmed
(646) 436-4702
aahmed@oysterpointrx.com

Media Contact
Karen Castillo-Paff
(347) 920-0248
kpaff@oysterpointrx.com

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

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 143,364	$ 193,372
Working capital*	$ 144,328	$ 186,448
Total assets	$ 176,720	$ 222,617
Long-term debt, net	$ 90,636	$ 89,815
Stockholders' equity	$ 55,993	$ 99,537

* 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 March 31,	
	2022	**2021**
	(unaudited)	
Revenue:		
Product revenue, net	$ 2,704	$ -
Total revenue	2,704	-
Cost of product revenue	336	-
Operating expenses:		
Sales and marketing	26,966	4,567
General and administrative	12,932	8,525
Research and development	4,681	5,828
Total operating expenses	44,579	18,920
Loss from operations	(42,211)	(18,920)
Other (expense) income:		
Interest expense	(3,066)	-
Other (expense) income, net	(2,615)	11
Total other (expense) income, net	(5,681)	11
Net loss and comprehensive loss	$ (47,892)	$ (18,909)
Net loss per share, basic and diluted	$ (1.80)	$ (0.73)
Weighted average shares outstanding, basic and diluted	26,631,577	25,924,096