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

August 11, 2022

- **TYRVAYA® (Varenicline Solution) Nasal Spray Achieved Net Product Revenue of $4.7 Million in Q2'22**
- **Approximately 30,000 TYRVAYA Prescriptions Filled During the Quarter, with Prescriptions Written by Over 5,700 Unique Eye Care Professionals; Launch to Date, Approximately 7,700 Unique Eye Care Professionals Have Written Prescriptions for TYRVAYA**
- **Expanded Patient Access to TYRVAYA, With Medicare Part D Access Expected by Q4'22, and As Early As September 2022**
- **Operating Expense Streamlining Plan to Maximize Commercial Potential of TYRVAYA and Create Value for Shareholders**
- **Continuing Enrollment of Subjects in the OLYMPIA Phase 2 Clinical Trial for Stage 1 Neurotrophic Keratopathy, with Study Results Expected in Q4'22**
- **Pre-IND Meeting Request Submitted to the U.S. FDA for Enriched Tear Film (ETF™) Gene Therapy to Target Stages 2 and 3 Neurotrophic Keratopathy**
- **Licensing Partner, Ji Xing Pharmaceuticals, Announced the First Patients Enrolled in the Phase 3 Clinical Trial of OC-01 (Varenicline Solution) Nasal Spray in China**
- **Conference Call and Webcast Scheduled for 4:30 pm ET Today**

PRINCETON, N.J., Aug. 11, 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 June 30, 2022, and provided an overview of recent business highlights.

"We are very pleased with Q2 results as we continue to execute on our TYRVAYA® commercialization strategy," said Jeffrey Nau, Ph.D., MMS, president and chief executive officer of Oyster Point Pharma. "We steadily grew TYRVAYA's footprint in the dry eye market, with expanded patient access and over 30,000 prescriptions written during the quarter. While our commercial team focused on increasing adoption of TYRVAYA, we also made significant progress across multiple areas of the business including collaborating with licensing partner Ji Xing Pharmaceuticals to enroll the first patients in the first Phase 3 trial of OC-01 outside of the U.S., continued enrollment of our OLYMPIA Phase 2 clinical trial for neurotrophic keratopathy and the submission of a Pre-IND meeting request to the U.S. FDA for our Enriched Tear Film gene therapy platform."

Recent Business Highlights

- **TYRVAYA (Varenicline Solution) Nasal Spray Achieved Net Product Revenue of $4.7 Million in Q2'22 with Approximately 30,000 Prescriptions Filled:** In Q2'22, the Company recognized $4.7 million in net product revenue related to sales of TYRVAYA Nasal Spray, which was launched in November 2021, representing quarter-over-quarter growth of 74%. Approximately 30,000 TYRVAYA prescriptions were filled during the second quarter of 2022. Prescriptions were written by over 5,700 unique eye care professionals during the quarter, reflecting the continued strong uptake of TYRVAYA, the first and only nasal spray approved for the treatment of the signs and symptoms of dry eye disease. As of July 22, 2022, over 62,000 prescriptions of TYRVAYA have been filled by approximately 7,700 unique prescribers since the product launched in November 2021.

- **Expanded Patient Access to TYRVAYA:** TYRVAYA is now covered by commercial prescription drug plans managed by the nation's top three Pharmacy Benefit Manager (PBM) Group Purchasing Organizations (GPOs). In July, the Company also introduced expanded patient access programs to include more eligible patients. For further details, please see the Company's patient access website at www.tyrvaya-pro.com. In addition, the Company expects to begin securing Medicare Part D access for TYRVAYA by Q4'22, and as early as September 2022.

- **Operating Expense Streamlining Plan:** On June 28, 2022, the Company announced a plan to streamline operating expenses, including a reduction in force. The purpose of the plan is to better align the Company's workforce with the anticipated current needs of its business, maximize the commercial potential of TYRVAYA and create value for the Company's stakeholders. As a result of the plan, the Company estimates that it will reduce operating expenses by approximately $6.0 million to $8.0 million, net of severance costs, in the second half of 2022, and reduce operating expenses by approximately $40.0 million to $48.0 million in 2023. The reduction in operating expenses is expected to be primarily driven by lower non-employee-related general and administrative and research and development expenses, and to a lesser extent, by the reduction of up to approximately 50 positions across the organization. These estimates are

subject to a number of assumptions, and actual results may differ.

- **Licensing Partner, Ji Xing Pharmaceuticals, Enrolled the First Patients in the Phase 3 Clinical Trial of OC-01 in China:** On July 22, 2022, Ji Xing Pharmaceuticals, a licensing partner of the Company, announced that the first patients have been enrolled in the Phase 3 clinical study of OC-01 (varenicline solution) nasal spray in China. The study will be carried out in over 20 leading clinical centers across China and is designed to evaluate the efficacy and safety of OC-01 nasal spray for the treatment of the signs and symptoms of dry eye disease to support a new drug application in China.

Upcoming Milestones

- **Continued Enrollment of Subjects in the OLYMPIA Phase 2 Clinical Trial for Stage 1 Neurotrophic Keratopathy (NK):** In Q2'22, 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 is continuing with study results expected in the fourth quarter of 2022.

- **Pre-IND Meeting Request submitted to the U.S. FDA for Enriched Tear Film (ETF^{TM}) Gene Therapy to Target Stages 2 and 3 Neurotrophic Keratopathy (NK):** In Q2'22, the Company progressed its pre-clinical program for the proprietary ETF^{TM} gene therapy OC-101 (AAV-NGF). OC-101 (AAV-NGF) is administered as 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. The goal of this approach is to harness the lacrimal gland as a bio-factory to secrete NGF with the natural tear film onto the ocular surface. In Q2'22, the Company completed a second preclinical study using a pig model, demonstrating that following AAV transduction of the lacrimal gland, significant human NGF was produced in the tear film for as long as 90 days (the last timepoint in the study). Cholinergic activation with OC-01 produced a significant increase of NGF levels in tear film, as compared to control, potentially indicating OC-01's ability to modulate lacrimal secretion of NGF. The Company has submitted a Pre-IND meeting request to the U.S. FDA for the OC-101 (AAV-NGF) program.

Overview of Financial and Operating Results

Second Quarter 2022 Financial Results

- **Cash Position:** As of June 30, 2022, cash and cash equivalents was $104.9 million, compared to $143.4 million as of March 31, 2022. The decrease in cash and cash equivalents during the three months ended June 30, 2022, of $38.5 million was primarily the result of amounts spent to fund operating activities incurred to market TYRVAYA Nasal Spray.

- **Product Revenues, Net:** Net product revenues for the three months ended June 30, 2022, were $4.7 million. TYRVAYA Nasal Spray was approved by the FDA on October 15, 2021, and commercially launched in the U.S. in November 2021. The Company did not generate any revenues from product sales during the three months ended June 30, 2021.

- **Cost of Product Revenue:** Cost of product revenue for the three months ended June 30, 2022, was $1.3 million and consisted of product royalty expenses, third-party manufacturing costs, reserves for inventory obsolescence and material costs.

- **Sales and Marketing Expenses:** Sales and marketing expenses increased by $21.9 million during the three months ended June 30, 2022, compared to the three months ended June 30, 2021. The increase was primarily due to higher payroll-related expenses of $11.4 million, which was driven by the growth of the Company's sales force since 2021. The increase in payroll-related expenses also included an increase in severance expense of $1.4 million due to the reduction in force announced on June 28, 2022. Other sales and marketing expenses increased by $10.5 million during the three months ended June 30, 2022, compared to the three months ended June 30, 2021, in connection with advertising, samples, trade shows, educational programs, patient services, payor access and other marketing efforts related to the commercialization of TYRVAYA Nasal Spray.

- **General and Administrative Expenses:** General and administrative expenses increased by $4.9 million during the three months ended June 30, 2022, compared to the three months ended June 30, 2021. The increase was primarily driven by additional payroll-related expenses of $3.0 million due to an increase in headcount to support the Company's business operations. The increase in payroll-related expenses also included an increase in severance expense of $0.5 million due to the reduction in force announced on June 28, 2022. Other general and administrative expenses increased by $1.9 million during the three months ended June 30, 2022, compared to the three months ended June 30, 2021, related to accounting, public relations, legal, insurance and other professional services. The increase in other general and administrative expenses was primarily driven by the Company's transition from a clinical-stage to a commercial-stage company.

- **Research and Development Expenses:** Research and development expenses decreased by $2.1 million during the three

months ended June 30, 2022, compared to the three months ended June 30, 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. This was partially offset by an increase in severance expense of $0.6 million due to the reduction in force announced on June 28, 2022.

- **Interest Expense:** The Company incurred interest expense of $3.2 million during the three months ended June 30, 2022, related to the Company's credit agreement with OrbiMed entered into in August 2021. Interest expense for the three months ended June 30, 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 June 30, 2021.

- **Other (Expense) Income, net:** Other expense for the three months ended June 30, 2022, of $3.4 million consisted of a $3.5 million change in the fair value of the net embedded derivative liability related to the Credit Agreement, partially offset by interest earned on money market funds. Other income for the three months ended June 30, 2021, primarily consisted of interest income earned on money market funds.

- **Net Loss:** For the three months ended June 30, 2022, the Company had a net loss of $49.9 million, or ($1.87) per share, compared to a net loss of $22.0 million, or ($0.85) per share, for the three months ended June 30, 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 second quarter 2022 financial results and provide a business update.

To access the live call by phone, please register here to receive dial-in details or to select a call back. The webcast will be made available on the company's website at www.oysterpointrx.com under the "Events & Presentations" section. A replay of the webcast will be available on the company's website.

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 insurance 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, and the availability and sufficiency of third-party payor coverage and reimbursement in connection with TYRVAYA; the Company's estimates associated with the Company's plan to streamline operating expenses, including the associated reduction in force, and any resulting savings benefits the Company expects to achieve; 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)

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 104,876	$ 193,372
Working capital*	$ 101,584	$ 186,448
Total assets	$ 143,935	$ 222,617
Long-term debt, net	$ 91,435	$ 89,815
Stockholders’ equity	$ 10,775	$ 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 June 30,		Six months ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Product revenue, net	$ 4,693	$ -	$ 7,397	$ -
Total revenue	4,693	-	7,397	-
Cost of product revenue	1,310	-	1,646	-
Operating expenses:				
Sales and marketing	28,103	6,210	55,075	10,777
General and administrative	14,004	9,086	26,930	17,611
Research and development	4,664	6,730	9,345	12,558
Total operating expenses	46,771	22,026	91,350	40,946
Loss from operations	(43,388)	(22,026)	(85,599)	(40,946)
Other (expense) income, net				
Interest expense	(3,156)	-	(6,222)	-
Other (expense) income, net	(3,398)	10	(6,013)	21
Total other (expense) income, net	(6,554)	10	(12,235)	21
Net loss and comprehensive loss	$ (49,942)	$ (22,016)	$ (97,834)	$ (40,925)
Net loss per share, basic and diluted	$ (1.87)	$ (0.85)	$ (3.67)	$ (1.58)
Weighted average shares outstanding, basic and diluted	26,744,008	25,989,913	26,688,103	25,957,186