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

November 10, 2022

- **TYRVAYA® (Varenicline Solution) Nasal Spray Achieved Net Product Revenue of $5.6 Million in Q3'22**
- **Approximately 34,000 TYRVAYA Prescriptions Filled During the Quarter, with Prescriptions Written by Approximately 6,100 Unique Eye Care Professionals**
- **November 1, 2022 Marked the First Anniversary of the Commercial Launch of TYRVAYA, with Over 97,000 Prescriptions Written as of October 21, 2022**
- **Expanded Patient Access and Commercial Coverage for TYRVAYA, with Up to Approximately 117 Million Lives Covered to Date**
- **Oyster Point Pharma to be Acquired by Viatris, with the Transaction Expected to Close During Q1'23**
- **Enrollment Completed in the OLYMPIA Phase 2 Clinical Trial for Stage 1 Neurotrophic Keratopathy, with Data Readout Expected in Q1'23**
- **Positive Pre-IND Meeting Feedback from the FDA to Advance Enriched Tear Film Gene (ETF™) Therapy Towards Clinical Studies for Stages 2 and 3 Neurotrophic Keratopathy**

PRINCETON, N.J., Nov. 10, 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 September 30, 2022, and provided an overview of recent business highlights.

"We are pleased with third quarter results while establishing TYRVAYA as the first and only nasal spray available as a treatment option for patients suffering from dry eye disease," said Jeffrey Nau, Ph.D., MMS, president and chief executive officer of Oyster Point Pharma. "We continued to grow TYRVAYA prescription volumes and net revenues, with approximately 34,000 prescriptions written during the quarter. We also achieved key development milestones including the completion of enrollment in our OLYMPIA Phase 2 clinical trial for stage 1 neurotrophic keratopathy and receiving positive pre-IND meeting feedback from the FDA for the OC-101 gene therapy program."

Recent Business Highlights

- **TYRVAYA (Varenicline Solution) Nasal Spray Achieved Net Product Revenue of $5.6 Million in Q3'22 with Approximately 34,000 Prescriptions Filled:** In Q3'22, the Company recognized $5.6 million in net product revenue related to sales of TYRVAYA Nasal Spray, which was launched in November 2021. Approximately 34,000 TYRVAYA prescriptions were filled during the third quarter of 2022. Prescriptions were written by approximately 6,100 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.

- **November 1, 2022 Marked the First Anniversary of the Commercial Launch of TYRVAYA, with Over 97,000 Prescriptions Written as of October 21, 2022:** Since TYRVAYA's commercial launch in November 2021, over 97,000 prescriptions of TYRVAYA have been filled by approximately 9,300 unique prescribers as of October 21, 2022, reflecting continued enthusiasm by eye care professionals.

- **Expanded Patient Access and Commercial Coverage for TYRVAYA:** Following coverage determinations for TYRVAYA from all major U.S. commercial payors as of July 2022, the Company has continued to expand patient access programs to include more eligible patients. According to MMIT, TYRVAYA now has commercial coverage for up to approximately 117 million lives, or 65% of all U.S. commercial lives.

- **Oyster Point Pharma to be Acquired by Viatris:** On November 7, 2022, the Company announced that it has entered into a definitive merger agreement with Viatris Inc. (Nasdaq: VTRS) ("Viatris"), a global healthcare company, pursuant to which Viatris would acquire the Company. Under the terms of the agreement, Viatris will initiate a tender offer to acquire all of the outstanding shares of the Company's common stock at a price of $11.00 per share in cash at closing, plus a contingent value right ("CVR") representing the right to receive a potential cash payment of up to $2.00 per share. The amount (if any) payable under the CVR will be based on the following performance targets to be achieved by the Company for full year 2022:

    - An additional $1.00 per share in cash if the Company generates equal to or greater than $21.6 million of net product revenue and 131,822 total prescriptions of TYRVAYA in the United States for the twelve months ended December 31, 2022; or

- An additional $2.00 per share in cash if the Company generates equal to or greater than $24.0 million of net product revenue and 146,469 total prescriptions of TYRVAYA in the United States for the twelve months ended December 31, 2022.

The transaction is anticipated to close during the first quarter of 2023, subject to the closing conditions provided in the merger agreement.

Development Milestones

- **Enrollment Completed in the OLYMPIA Phase 2 Clinical Trial for Stage 1 Neurotrophic Keratopathy (NK), with Data Readout Expected in Q1'23 :** In October 2022, the Company completed enrollment of patients in the OLYMPIA Phase 2 clinical trial of OC-01 (varenicline solution) nasal spray for the treatment of Stage 1 NK, with a data readout expected in the first quarter of 2023. Total enrollment in the study was 113 subjects at 34 U.S. centers, slightly more than the original target of 100 subjects. In the OLYMPIA Phase 2 clinical trial, OC-01 (varenicline solution) nasal spray is administered three times daily and will be compared to placebo (vehicle) nasal spray. The pre-specified primary endpoint of the trial is the mean change from baseline in corneal fluorescein staining in subjects with Stage 1 NK at Day 56.

- **Positive Pre-IND Meeting Feedback from the FDA to Advance Enriched Tear Film (ETF ™) Gene Therapy Towards Clinical Studies for Stages 2 and 3 Neurotrophic Keratopathy:** In Q3'22, the Company received positive pre-IND meeting feedback from the U.S. FDA for the proprietary ETF™ gene therapy candidate, OC-101 (AAV-NGF), which 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 Company will commence IND-enabling studies in order to advance the program into clinical studies. During the third quarter of 2022, the Company also disclosed an additional target and further indications for its ETF gene therapy program. Pre-clinical studies are underway with an AAV vector containing diamine oxidase (DAO), a key enzyme involved in histamine degradation, for the treatment of Atopic Keratoconjunctivitis (AKC) and Vernal Keratoconjunctivitis (VKC).

Overview of Financial and Operating Results

Third Quarter 2022 Financial Results

- **Cash Position:** As of September 30, 2022, cash and cash equivalents was $68.8 million, compared to $104.9 million as of June 30, 2022. The decrease in cash and cash equivalents during the three months ended September 30, 2022, of $36.1 million was primarily the result of amounts spent to fund marketing activities for TYRVAYA Nasal Spray.

- **Product Revenues, Net:** Net product revenues for the three months ended September 30, 2022 were $5.6 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 September 30, 2021.

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

- **Sales and Marketing Expenses:** Sales and marketing expenses increased by $3.9 million during the three months ended September 30, 2022, compared to the three months ended September 30, 2021. The increase was primarily due to higher payroll-related expenses of $3.1 million, which was driven by the growth of the Company's sales force since 2021. Other sales and marketing expenses increased by $0.8 million during the three months ended September 30, 2022, compared to the three months ended September 30, 2021, in connection with 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 $1.8 million during the three months ended September 30, 2022, compared to the three months ended September 30, 2021. The increase was primarily driven by additional payroll-related expenses of $2.7 million due to an increase in headcount to support the Company's business operations, including an increase in stock compensation expenses of $0.8 million. Other general and administrative expenses decreased by $0.9 million during the three months ended September 30, 2022, compared to the three months ended September 30, 2021, primarily related to a decrease in sponsorships, public relations and recruiting activities.

- **Research and Development Expenses:** Research and development expenses decreased by $2.3 million during the three months ended September 30, 2022, compared to the three months ended September 30, 2021. The decrease was primarily due to decreased research and development activity relating to OC-01 (varenicline solution) nasal spray following its approval by the FDA on October 15, 2021, and lower payroll-related expenses of $0.7 million.

- **Interest Expense:** The Company incurred $3.5 million and $1.1 million of interest expense during the three months ended September 30, 2022 and 2021, respectively, related to the Company's credit agreement with OrbiMed originally entered into in August 2021. Interest expense for both periods included contractual interest, as well as the amortization of loan commitment fees and accretion of other long-term debt related costs.

- **Other Income, net:** Other income for the three months ended September 30, 2022 of $0.7 million consisted of a $0.4 million change in the fair value of the net embedded derivative liability related to the Company's credit agreement with OrbiMed in addition to interest earned on money market funds. Other income for the three months ended September 30, 2021 primarily consisted of $0.2 million of income associated with the change in the fair value of the net embedded derivative liability, as well as interest income earned on money market funds.

- **Net Loss:** For the three months ended September 30, 2022, the Company had a net loss of $36.7 million, or ($1.37) per share, compared to a net loss of $17.7 million, or ($0.68) per share, for the three months ended September 30, 2021.

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

To the extent that statements contained in this press release are not statements of historical facts, they may be deemed to be forward-looking statements. In some cases, such forward-looking statements can be identified by terms such as "believes," "plans," "anticipates," "continue," "potential," "seek," "goal," "projects," "estimates," "expects," "intends," "strategy," "future," "opportunity," "may," "will," "should," "could," "potential," or similar expressions. Such forward-looking statements are based on management's current expectations, beliefs, estimates, projections and assumptions. As such, forward-looking statements are not guarantees of future performance and involve inherent risks and uncertainties that are difficult to predict. As a result, a number of important factors could cause actual results to differ materially from those indicated by such forward-looking statements, including: the risk that the proposed acquisition of Oyster Point Pharma Inc. ("OP") by Viatris Inc. ("Parent") may not be completed; the possibility that competing offers or acquisition proposals for OP will be made; the delay or failure of the tender offer conditions to be satisfied (or waived), including insufficient shares of OP common stock being tendered in the tender offer; the failure (or delay) to receive the required regulatory approvals of the proposed acquisition; the possibility that prior to the completion of the transactions contemplated by the acquisition agreement, Parent's or OP's business may experience significant disruptions due to transaction-related uncertainty; the effects of disruption from the transactions of OP's business and the fact that the announcement and pendency of the transactions may make it more difficult to establish or maintain relationships with employees, manufacturers, suppliers, vendors, business partners and distribution channels to patients; the occurrence of any event, change or other circumstance that could give rise to the termination of the acquisition agreement; the risk that stockholder litigation in connection with the proposed transaction may result in significant costs of defense, indemnification and liability; the failure of the closing conditions set forth in the acquisition agreement to be satisfied (or waived); the possibility that OP's expectations as to the extent to which OP will be able to continue to commercialize TYRVAYA® (varenicline solution) Nasal Spray and any of OP's other products and product candidates may not be realized as anticipated; the possibility that the anticipated scope, rate of progress and cost of OP's preclinical studies and clinical trials and other research and development that OP may not materialize; the possibility that OP's estimates of its expenses, ongoing losses, future revenue, capital requirements and its needs for or ability to obtain additional financing may not be accurate; the possibility that OP's expectations may not be met as to the sufficiency of its capital resources; the possibility that OP's expectations may not be met as to its ability to obtain and maintain intellectual property protection for its

products and any of its product candidates; the possibility that OP's anticipated receipt and timing of royalties from its collaborators may not be realized as anticipated; the possibility that OP's expectations may not be met as to the revenues from its collaborations; the possibility that OP's expectations may not be met as to OP's ability to retain and recruit key personnel and third-party distributors; the possibility that OP's expectations may not be met as to its anticipated financial performance; the possibility that OP's expectations may not be met as to its anticipated developments and projections relating to its competitors or the industry in which OP operates; the possibility that unforeseen safety issues could emerge for TYRVAYA Nasal Spray that could require OP to change the prescribing information, limit use of the product and/or result in litigation; the possibility that other manufacturers could obtain approval for generic versions of TYRVAYA Nasal Spray or of products with which OP competes; the possibility that the third-party organizations that manufacture, supply and distribute TYRVAYA Nasal Spray may fail to perform adequately or fulfill OP's needs; the possibility that changes in healthcare law and implementing regulations may occur and may negatively impact OP's ability to generate revenues or could limit or prevent OP's products' or product candidates' commercial success; the possibility that regulatory filings for products or product candidates that OP or its partners develop are not made or granted as currently anticipated; the possibility that OP is not able to negotiate adequate pricing, coverage and adequate reimbursement for its products and product candidates with third parties and government authorities; the possibility of political, social and economic instability, natural disasters or public health epidemics in countries where OP or its collaborators conduct activities related to OP's business; and a variety of other risks set forth from time to time in Parent's or OP's filings with the SEC, including but not limited to the risks discussed in Parent's Annual Report on Form 10-K for the year ended December 31, 2021 and in other filings with the SEC and the risks discussed in OP's Annual Report on Form 10-K for the year ended December 31, 2021 and in its other filings with the SEC. The risks and uncertainties may be amplified by the COVID-10 pandemic, which has caused significant economic uncertainty. The extent to which the COVID-19 pandemic impacts Parent's and OP's businesses, operations and financial results, including the duration and magnitude of such effects, will depend on numerous factors, which are unpredictable, including, but not limited to, the duration and spread of the outbreak, its severity, the actions to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume. The reader is cautioned not to unduly rely on these forward-looking statements. Parent and OP expressly disclaim any intent or obligation to update or revise publicly these forward-looking statements except as required by law.

Additional Information about the Transaction and Where to Find It

The tender offer for the outstanding common stock of Oyster Point Pharma Inc. ("OP") has not yet been commenced. This press release does not constitute a recommendation, an offer to purchase or a solicitation of an offer to sell OP securities. At the time the tender offer is commenced, Viatris Inc. ("Parent") and Iris Purchaser Inc., a direct wholly owned subsidiary of Parent ("Purchaser"), will file a Tender Offer Statement on Schedule TO (including an Offer to Purchase) with the Securities and Exchange Commission (the "SEC") and thereafter, OP will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC, in each case, with respect to the Tender Offer. The solicitation and the offer by Parent to purchase shares of OP's common stock will only be made pursuant to such Offer to Purchase and related materials. Once filed, investors and security holders are urged to read these materials (including the Offer to Purchase, a related Letter of Transmittal and certain other tender offer documents, as each may be amended or supplemented from time to time) carefully since they will contain important information that OP investors and security holders should consider before making any decision regarding tendering their common stock, including the terms and conditions of the tender offer. The Tender Offer Statement, Offer to Purchase, Solicitation/Recommendation Statement and related materials will be filed with the SEC, and OP investors and security holders may obtain a free copy of these materials (when available) and other documents filed by Parent, Purchaser and OP with the SEC at the website maintained by the SEC at www.sec.gov. In addition, the Tender Offer Statement and other documents that Parent and Purchaser file with the SEC will be made available to all investors and security holders of OP free of charge from the information agent for the tender offer. Investors may also obtain, at no charge, the documents filed with or furnished to the SEC by OP under the "Investors & Media" section of OP's website at https://oysterpointrx.com.

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)
(unaudited)

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 68,800	$ 193,372
Working capital*	$ 68,510	$ 186,448
Total assets	$ 109,201	$ 222,617
Long-term debt, net	$ 92,218	$ 89,815

Stockholders' equity (deficit)	$ (22,202)	$ 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 September 30,		Nine months ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Product revenue, net	$ 5,591	$ -	$ 12,988	$ -
License revenue - related party	-	17,943	-	17,943
Total revenue	5,591	17,943	12,988	17,943
Cost of product revenue	1,348	-	2,994	-
Operating expenses:				
Sales and marketing	22,094	18,170	77,169	28,947
General and administrative	12,149	10,327	39,079	27,938
Research and development	3,913	6,214	13,258	18,772
Total operating expenses	38,156	34,711	129,506	75,657
Loss from operations	(33,913)	(16,768)	(119,512)	(57,714)
Other (expense) income				
Interest expense	(3,495)	(1,124)	(9,717)	(1,124)
Other income (expense), net	661	222	(5,352)	243
Total other (expense) income, net	(2,834)	(902)	(15,069)	(881)
Net loss and comprehensive loss	$ (36,747)	$ (17,670)	$ (134,581)	$ (58,595)
Net loss per share, basic and diluted	$ (1.37)	$ (0.68)	$ (5.03)	$ (2.25)
Weighted average shares outstanding, basic and diluted	26,830,756	26,037,975	26,736,177	25,984,412