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

May 6, 2021

- **PDUFA Target Action Date for OC-01 (varenicline) Nasal Spray is October 17, 2021**
- **Planned U.S. Launch of OC-01 (varenicline) Nasal Spray in Q4 2021, if approved by the FDA**
- **OLYMPIA Phase 2 Study on Track, with Planned Enrollment of the First Patient in 1H 2021**
- **Continued Organizational Advancement Towards Commercialization**
- **Conference Call and Webcast Scheduled for 4:30 pm ET Today**

PRINCETON, N.J., May 06, 2021 (GLOBE NEWSWIRE) -- Oyster Point Pharma, Inc. (Nasdaq: OYST), ("Oyster Point Pharma", or "the Company"), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases, announced its financial results for the first quarter of 2021, and provided an overview of recent business highlights.

“The Oyster Point Pharma team is focused on preparing for a potential launch of OC-01 nasal spray, if approved, while also continuing our clinical development and R&D programs. I am looking forward to 2021 being an inflection point for Oyster Point Pharma as a leader in the ocular surface disease space," said Jeffrey Nau, Ph.D., MMS president and chief executive officer of Oyster Point Pharma. Dr. Nau continued, "We are excited to build a team dedicated to helping patients who often have limited or no treatment options. Oyster Point Pharma is committed to continued innovation to change the lives of patients.”

Recent Business Highlights

- **Announced FDA Acceptance for Filing of New Drug Application for OC-01 (varenicline) Nasal Spray for the Treatment of Signs and Symptoms of Dry Eye Disease:** The Prescription Drug User Fee Act (PDUFA) target action date is October 17, 2021, with a planned U.S. launch of OC-01 (varenicline) nasal spray in the fourth quarter of 2021, if approved by the U.S. Food and Drug Administration (FDA). The FDA stated that it does not intend to hold an advisory committee meeting to discuss this application. The Company submitted its 505(b)(2) NDA to the FDA for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease on December 17, 2020.

- **OLYMPIA Phase 2 Study on Track:** Enrollment of the first patient in the OLYMPIA Phase 2 study of OC-01 (varenicline) nasal spray in Neurotrophic Keratopathy (NK) remains on track for the first half of 2021. NK is the second of a number of important potential indications the Company is evaluating with OC-01 (varenicline) nasal spray, underscoring the Company's commitment to treating unmet needs related to ocular surface diseases.

- **Continued Organizational Advancement Towards Commercialization:** The Company continues to make meaningful progress toward its planned U.S. launch of OC-01 (varenicline) nasal spray in the fourth quarter of 2021, if approved by the FDA, including the addition of key talent in commercial operations, market access and marketing areas.

Overview of Financial and Operating Results

First Quarter 2021 Financial Results

- **Cash Position:** As of March 31, 2021, cash and cash equivalents were $175.9 million, compared to $192.6 million as of December 31, 2020.

- **R&D Expenses:** Research and development expenses decreased by $5.5 million during the three months ended March 31, 2021 compared to the three months ended March 31, 2020. The Company's clinical and preclinical expense was $4.2 million lower during the first quarter of 2021 primarily due to the completion of the ONSET-2 Phase 3 clinical trial in May 2020. The Company's chemistry, manufacturing and controls expense increased $1.8 million primarily due to the continued advancement of OC-01 (varenicline) nasal spray and anticipated commercial launch, if approved by the FDA. The $3.1 million decrease in other research and development expenses was primarily due to the Company recording a $2.9 million gain in the first quarter of 2021 in connection with the small business waiver granted by the FDA for the NDA application fee in February 2021. The NDA application fee was paid and expensed in December 2020, and subsequently refunded by the FDA in April 2021.

- **SG&A Expenses:** Selling, general and administrative expenses increased by $7.5 million during the three months ended March 31, 2021 compared to the three months ended March 31, 2020. The increase was primarily driven by additional payroll-related expenses of $4.6 million due to an increase in headcount, as well as higher commercial planning expenses of $1.7 million in anticipation of a U.S. launch of OC-01 (varenicline) nasal spray, if approved, in the fourth quarter of 2021. Additionally, there was an increase in other general and administrative expenses of $1.2 million due to an increase in costs for administrative and professional service fees and certain medical affairs costs.

- **Net Loss:** For the first quarter of 2020, the Company had a net loss of $18.9 million, or $(0.73) per share, compared to a net loss of $16.5 million, or $(0.77) 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 first 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 9384288. The webcast will be made available on the company's website at www.oysterpointrx.com under the "Events & Presentations" section of the company's website at https://edge.media-server.com/mmc/p/sn78s9u4.

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 9384288.

About Oyster Point Pharma, Inc.

Oyster Point Pharma is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases. Oyster Point Pharma's lead product candidate, OC-01 (varenicline) nasal spray, a highly selective cholinergic agonist, is being developed as a nasal spray to treat the signs and symptoms of dry eye disease and neurotrophic keratopathy. In preclinical and clinical studies, OC-01 (varenicline) nasal spray was shown to have a novel mechanism of action via activation of the trigeminal parasympathetic pathway to stimulate the glands and cells responsible for natural tear film production, known as the lacrimal functional unit.

About OC-01 (varenicline) Nasal Spray

OC-01 (varenicline) nasal spray is a highly selective cholinergic agonist being developed as a multidose preservative-free nasal spray to treat the signs and symptoms of dry eye disease and neurotrophic keratopathy. 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. Administered as a preservative-free, aqueous nasal spray, in pre-clinical and clinical studies, OC-01 (varenicline) nasal spray was shown to have a novel mechanism of action with activation of the trigeminal parasympathetic pathway in the nasal cavity to stimulate natural tear film production. 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. This complex tear film is responsible for forming the primary refracting surface of the eye, as well as protecting and moisturizing the cornea. OC-01 (varenicline) nasal spray is an investigational new drug and has not been approved for any use in any country. The safety and efficacy of OC-01 (varenicline) nasal spray have not previously been established.

About Dry Eye Disease

Dry eye disease is a chronic, progressive condition that impacts more than 30 million people in the United States (U.S.) and is growing in prevalence. An estimated 16 million adults in the U.S. have been diagnosed with dry eye disease, a multifactorial condition of the ocular surface characterized by disruption of the tear film. A healthy tear film protects and lubricates the eyes, washes away foreign particles, contains growth factors and antimicrobial components to reduce the risk of infection, and creates a smooth surface that contributes refractive power for clear vision. Dry eye disease can have a significant impact on a person's day-to-day quality of life, as it can cause persistent stinging, scratching, burning sensations, sensitivity to light, blurred vision, and eye fatigue. Despite the large prevalence of dry eye and the burden of the disease, there remains a significant unmet need for effective therapies.

About Neurotrophic Keratopathy

Neurotrophic Keratopathy (NK), is a disease characterized by decreased corneal sensitivity and poor corneal healing. The most common causes of loss of corneal sensation are viral infection (herpes simplex and herpes zoster keratoconjunctivitis) followed by chemical burns, physical injuries, and corneal surgery. In addition, systemic diseases such as diabetes and multiple sclerosis may decrease sensory nerve function or damage sensory fibers. NK can be classified broadly into three stages: Stage 1 (mild) consists of ocular surface irregularities and reduced vision, Stage 2 (moderate) exhibits a non-healing persistent defect of the corneal epithelium, and Stage 3 (severe) exhibits corneal ulceration, which may progress to corneal melting and perforation. If not adequately addressed, the progression of NK can lead to the loss of the cornea and the need for transplantation.

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 the "Company regarding the future of the Company's business, our future plans and strategies, regulatory approvals, 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 clinical trials, and their timing and likelihood of success, 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: the timing or likelihood of regulatory filings and approvals for our product candidates; our ability to obtain and maintain regulatory approvals of our product candidates; our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy; the success of competing therapies that are or may become available; the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates; our plans relating to the further development and manufacturing of our product candidates, including additional indications or disease areas to be evaluated and pursued; the impact of the

COVID-19 pandemic on our business, operations, and regulatory and clinical development timelines, plans and expectations; the prevalence of dry eye disease and Neurotrophic Keratopathy (NK) and the size of the market opportunities for our product candidates; the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates, and other positive results; the timing of initiation of our future clinical trials, and the reporting of data from our current and future trials; 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 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). The Company is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

Investor Contact
Tim McCarthy
LifeSci Advisors, LLC
(212) 915-2564
investors@oysterpointrx.com

Media Contact
Sheryl Seapy, W2O Group
(213) 262-9390
sseapy@w2ogroup.com

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

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 175,910	$ 192,585
Working capital*	$ 168,912	$ 185,385
Total assets	$ 184,772	$ 197,910
Stockholders’ equity	$ 170,648	$ 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 March 31,	
	2021	2020
	(unaudited)	
Research and development:		
Clinical, preclinical	$ 1,935	$ 6,112
Chemistry, manufacturing and controls	5,625	3,837
Other	(1,732)	1,391
Total research and development	5,828	11,340
Selling, general and administrative	13,092	5,589
Loss from operations	(18,920)	(16,929)
Other income, net	11	410
Net loss and comprehensive loss	$ (18,909)	$ (16,519)
Net loss per share, basic and diluted	$ (0.73)	$ (0.77)

Weighted average shares outstanding, basic and diluted	25,924,096	21,367,532