Oyster Point Pharma Reports First Quarter 2020 Financial Results and Recent Business Highlights

May 11, 2020

Announces Positive Results in ONSET-2 Phase 3 Trial of OC-01 Nasal Spray for the Treatment of the Signs and Symptoms of Dry Eye Disease

ONSET-2 Data Enables NDA Submission in 2H 2020

Cash and Cash Equivalents of $128.6 million as of March 31, 2020

Conference Call and Webcast Scheduled for 8:00 am ET

PRINCETON, N.J., May 11, 2020 (GLOBE NEWSWIRE) -- Oyster Point Pharma, Inc. (Nasdaq: OYST), 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 2020, positive top-line results from the ONSET-2 Phase 3 study in dry eye disease, and provided an overview of recent business highlights.

Jeffrey Nau, PhD, MMS CEO, Oyster Point Pharma, said, “The ability to show statistically significant sign and symptom endpoints within the same clinical trial has been elusive in dry eye disease. ONSET-1 and ONSET-2 have independently met endpoints of both signs and symptoms in their respective trial populations. The ability to meet this high bar in the ONSET-2 population consisting of mild, moderate, and severe subjects is even more notable and speaks to the broad applicability of OC-01 to treat dry eye patients. We look forward to submitting the New Drug Application to FDA for OC-01 nasal spray to treat signs and symptoms of dry eye disease in the second half of 2020. If approved by the FDA, we remain on track for a planned U.S. launch in the fourth quarter of 2021.”

Recent Business Highlights

- **ONSET-2 Phase 3 Positive Top-line Results**: Today, Oyster Point Pharma released positive top-line results from the ONSET-2 Phase 3 study, which met the prespecified primary endpoint in both doses tested, and key secondary symptom endpoints in the 1.2 mg/ml dose group, which showed symptom improvement at Week 4 and as early as Week 2 compared to control. OC-01 was well-tolerated in the ONSET-2 clinical trial, and the adverse event profile was consistent with the safety profile seen in the ONSET-1 clinical trial. ONSET-2 was a multicenter, randomized, double-masked, vehicle-controlled Phase 3 clinical trial designed to evaluate the safety and efficacy of OC-01 (varenicline) nasal spray for the signs and symptoms of dry eye disease. The study enrolled 758 subjects at 22 centers in the United States and investigated two doses of OC-01 nasal spray, 0.6 mg/ml and 1.2 mg/ml, as compared to control (vehicle) nasal spray. Subjects were administered OC-01 nasal spray twice daily for 4 weeks.

- **MYSTIC Phase 2 Positive Top-line Results**: In January 2020, Oyster Point Pharma released top-line results from its Phase 2 MYSTIC study. Top-line results demonstrated that OC-01 nasal spray showed a statistically significant improvement in Schirmer’s Score at Day 84 in both doses tested compared to vehicle control nasal spray. The MYSTIC study was a randomized, single-masked, vehicle-controlled Phase 2 clinical trial that evaluated the safety and efficacy of OC-01 in 123 subjects with dry eye disease. The study compared two different doses of OC-01 nasal spray to vehicle control nasal spray (1:1:1 randomization). The goal of this study was to assess the safety and efficacy of twice daily dosing of OC-01 nasal spray administered for 84 days. The pre-specified primary endpoint was the assessment of tear production as measured by mean change in Schirmer’s Score at Day 84 as compared to vehicle control.

- **Strengthened Commercial Leadership Team**: Oyster Point Pharma continues to build upon its internal capabilities with new hires across the organization. In January 2020, the company added senior professionals to further support commercial planning capabilities in the Sales and Commercial Operations and the Market Access, Trade, and Patient Services teams, and to reinforce its existing Marketing capabilities. Following today’s positive results from the ONSET-2 study, Oyster Point Pharma will continue to execute on its launch readiness plan.

First Quarter 2020 Financial Results

- **R&D Expenses**: Total research and development expenses for the first quarter of 2020 were $11.3 million compared to $2.4 million for the same period in 2019. The increase in research and development expenses was primarily due to clinical development of OC-01 and reflected an increase in expense due to CROs and CMOs of $7.8 million and an increase in payroll and personnel-related expenses, including salaries and bonuses, benefits and stock-based compensation expense, of $1.1 million.

- **G&A Expenses**: Total general and administrative expenses for the first quarter of 2020 were $5.6 million compared to $1.6 million for the same period in 2019. The increase in general and administrative expenses was primarily due to the expansion of the organization and reflected an increase in payroll and personnel-related expenses, including salaries and bonuses, benefits and stock-based compensation expense, of $2.0 million, an increase in professional services and other expenses to support our operations as a public company of $1.8 million, and an increase in marketing expenses of $0.2 million.

- **Net Loss**: For the first quarter of 2020, Oyster Point Pharma had a net loss of $16.5 million, or $0.77 per share, compared to a net loss of $3.8 million, or $2.66 per share, for the same period in 2019.

- **Cash Position**: As of March 31, 2020, cash and cash equivalents were $128.6 million, compared to $139.1 million as of December 31, 2019.

Conference Call Details and Webcast
Oyster Point Pharma will host a live conference call and webcast today at 8:00 am Eastern Time to discuss the ONSET-2 top-line data, the first quarter 2020 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 6356809. 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/dnqsj6eh.

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 6356809**.** A replay of the webcast will be available for approximately 30 days following the live audio webcast.

About Oyster Point Pharma
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 nasal spray, a highly selective nicotinic acetylcholine receptor (nAChR) agonist, is being developed to treat the signs and symptoms of dry eye disease. OC-01 nasal spray's novel mechanism of action is designed to re-establish tear film homeostasis by activating the trigeminal parasympathetic pathway to stimulate the glands and cells responsible for natural tear film production, known as the lacrimal functional unit (LFU).

About Dry Eye Disease
Dry eye disease is a chronic, progressive condition that impacts more than 30 million Americans and is growing in prevalence. An estimated 16 million U.S. adults 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.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions and on information currently available to us. The forward-looking statements in this press release represent our views as of the date of this press release. These statements may include but are not limited to statements regarding future events or future financial and operating performance and our plans for and the anticipated benefits of new hires, our product candidates, the timing, objectives and results of the clinical studies and anticipated regulatory and development milestones, including potential timing of NDA submission and potential commercialization. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Important factors that could cause our actual results to differ materially are detailed from time to time in the "Risk Factors" section in reports we file with the Securities and Exchange Commission, copies of which are posted on our website and are available from us without charge. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties.

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

	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 128,630	$ 139,147
Working capital*	$ 121,253	$ 136,781
Total assets	$ 132,312	$ 143,209
Stockholders' equity	$ 121,963	$ 137,298

* 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)
(unaudited)

	Three months ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 11,340	$ 2,405
General and administrative	5,589	1,605
Total operating expenses	16,929	4,010
Loss from operations	(16,929)	(4,010)
Interest income	410	250
Net loss and comprehensive loss	$ (16,519)	$ (3,760)
Net loss per share, basic and diluted	$ (0.77)	$ (2.66)
Weighted average shares outstanding, basic and diluted	21,367,532	1,411,966

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