



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

August 5, 2021

- **PDUFA Target Action Date for OC-01 (varenicline) Nasal Spray is October 17, 2021**
- **Initiated Hiring of U.S. Sales Representatives in July, with a Planned U.S. Launch of OC-01 (varenicline) Nasal Spray in Q4'21, if Approved by the FDA**
- **Exclusive License Agreement with Ji Xing Pharmaceuticals to Develop and Commercialize OC-01 and OC-02 in Greater China, Providing \$17.5M Upfront, up to \$204.8M in Potential Development and Sales-Based Milestones, and Up to 0.75% Equity in Ji Xing Pharmaceuticals**
- **Entered Into \$125M Term Loan Credit Facility with OrbiMed, with \$45M Upfront and \$50M Upon FDA Approval of OC-01 (varenicline) Nasal Spray, if Approved**
- **Conference Call and Webcast Scheduled for 4:30 pm ET Today**

PRINCETON, N.J., Aug. 05, 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 ophthalmic diseases, today announced its financial results for the second quarter of 2021, and provided an overview of recent business highlights.

"Oyster Point Pharma has seen significant executional progress to date including commercial planning, business development, and financing activities along with meaningful R&D progress. In addition to the Company preparing for the potential launch of OC-01 (varenicline) nasal spray in Q4'21, we have announced the first subject enrolled in the OLYMPIA Phase 2 clinical trial and have announced additional pre-clinical programs to the expanding pipeline." said Jeffrey Nau, Ph.D., MMS president and chief executive officer of Oyster Point Pharma. Dr. Nau continued, "We are also excited to be building our commercial field force and capabilities as we welcome our first sales representatives to Oyster Point Pharma in July, with our mission to provide a novel therapeutic treatment for dry eye disease patients in Q4'21, if approved by the FDA."

Recent Business Highlights

- **Initiated Hiring of U.S. Sales Representatives in July:** 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, by initiating the hiring of sales representatives during the month of July, with a planned target of hiring 150-200 sales representatives. Sales representatives are currently in the field communicating our dry eye disease-state awareness campaign.
- **Announced Exclusive License Agreement with Ji Xing Pharmaceuticals to Develop and Commercialize OC-01 and OC-02 in Greater China:** On August 5, 2021, the Company announced an exclusive license and collaboration agreement with Ji Xing Pharmaceuticals (Ji Xing), a biotechnology company headquartered in Shanghai and founded by RTW Investments, LP (RTW), focused on bringing breakthrough medicines to underserved Chinese patients, to develop and, if approved, commercialize OC-01 (varenicline) and OC-02 (simpinicline) nasal sprays for the treatment of signs and symptoms of dry eye disease for patients in Greater China. Oyster Point will receive an upfront cash payment of \$17.5 million and up to 0.75% equity in Ji Xing. In addition, Oyster Point is eligible to receive up to \$204.8 million in potential development and sales-based milestone payments, as well as tiered royalty payments based on future net sales. Ji Xing will be responsible for the development and commercialization costs in Greater China.
- **Entered Into \$125 Million Term Loan Credit Facility with OrbiMed:** On August 5, 2021, the Company entered into a \$125 million term loan credit facility with OrbiMed Royalty & Credit Opportunities III, LP. The Credit Agreement provides for loans to be funded in three separate tranches, the first \$45 million tranche to be funded upfront, no later than August 13, 2021, the second \$50 million tranche to be funded upon FDA approval of OC-01 nasal spray, and the third \$30 million tranche to be funded upon meeting a net recurring sales threshold. The Credit Agreement matures in August 2027 and the loan is structured for full principal repayment at maturity. J. Wood Capital Advisors acted as the exclusive financial adviser to the Company for the financing.
- **Announced Enrollment of First Subject in the OLYMPIA Phase 2 Clinical Trial of OC-01 (varenicline) Nasal Spray**

for Patients with Neurotrophic Keratopathy: In June 2021, the Company announced enrollment of the first subject in the OLYMPIA Phase 2 clinical trial of OC-01 (varenicline) nasal spray for the treatment of Stage 1 Neurotrophic Keratopathy (NK).

- **Held Inaugural Analyst Day 2021 in July:** The Company continues to progress its R&D pipeline and in July, provided an update on its progress at an Analyst Day. A replay of the Analyst Day webcast and the slide presentation can be found at the Events & Presentations section of Oyster Point Pharma's corporate website.
- **Announced Pipeline Expansion with Enriched Tear Film (ETF™) Gene Therapy to Target Ophthalmic Diseases:** In June 2021, the Company announced the expansion of its pipeline with the introduction of its proprietary ETF™ gene therapy and proof-of-concept in vivo study results from its first gene therapy candidate, OC-101. Preclinical study results from a 42-day proof-of-concept in vivo study demonstrated a single, intralacrimal gland injection of an adeno-associated virus (AAV) vector that delivers the human Nerve Growth Factor (NGF) gene. A single injection produced statistically significant increase of NGF in tear film, as compared to control. Preclinical study results also demonstrated that following AAV transduction of the lacrimal gland, cholinergic activation with OC-01 (varenicline) nasal spray produced statistically significant increase of NGF levels in tear film of a rabbit model, as compared to control, and pre-cholinergic activation, potentially indicating OC-01's ability to modulate lacrimal secretion of NGF. No macroscopic or microscopic safety findings were observed associated with either the intralacrimal gland administration of OC-01 or intranasal administration of OC-01.
- **Announced Research Collaboration with Adaptive Phage Therapeutics, Inc. to Target Ophthalmic Diseases:** In May 2021, the Company entered into a research collaboration with Adaptive Phage Therapeutics, Inc. to develop biological therapies potentially targeting multiple bacterial diseases of the eye. Under the terms of the agreement, the Company has the option and certain rights to obtain an exclusive license to develop and commercialize technology for ophthalmic diseases and disorders. Under the license terms, if such an option is exercised, the Company would pay for potential development and regulatory milestones, as well as potential sales-related milestones and tiered royalties of net sales, if a licensed therapy is approved by the FDA or certain other regulatory authorities.
- **Announced Preclinical Data Highlighting Potent Activity of OC-01 (varenicline) and OC-02 (simpinicline) against SARS-CoV-2 Virus and Variants:** In July 2021, the Company announced preclinical data in non-human primates and in vitro models evaluating OC-01 (varenicline) nasal spray against SARS-CoV-2 and the alpha and beta variants, the viruses that cause COVID-19 disease. Administration of OC-01 (varenicline) nasal spray to non-human primates was observed to inhibit viral replication in the nose within 24 hours of infectious SARS-CoV-2 challenge with absence of subgenomic RNA at Day 3 and Day 5 post-challenge. The results were published on the preprint server bioRxiv. In addition, varenicline was observed to inhibit cellular entry and replication of SARS-CoV-2 and its alpha and beta variants in multiple human cell types. Lastly, OC-02 (simpinicline) was also observed to inhibit cellular entry and replication of SARS-CoV-2 alpha variant in Calu-3 human cells at very low concentrations. Additional preclinical studies with SARS-CoV-2 variants are currently underway.

Overview of Financial and Operating Results

Second Quarter 2021 Financial Results

- **Cash Position:** As of June 30, 2021, cash and cash equivalents were \$154.8 million, compared to \$192.6 million as of December 31, 2020.
- **R&D Expenses:** Research and development expenses decreased by \$1.8 million during the three months ended June 30, 2021 compared to the three months ended June 30, 2020. The decrease was primarily driven by lower CMC expenses incurred by the Company in the second quarter of 2021 compared to the second quarter of 2020, which included significant pre-approval inventory costs, as well as expenses related to the preparation of the NDA filing in December 2020.
- **SG&A Expenses:** Selling, general and administrative expenses increased by \$8.4 million during the three months ended June 30, 2021 compared to the three months ended June 30, 2020. The increase was driven by higher payroll-related expenses, including stock-based compensation of \$4.8 million, due to additional headcount, as well as higher commercial planning expenses of \$1.8 million in anticipation of a U.S. launch of OC-01 (varenicline) nasal spray, if approved, in the fourth quarter of 2021. In addition, the Company incurred higher other general and administrative expenses of \$1.0 million, related to accounting, legal, facilities, information technology, and other office-related costs. The Company also incurred an increase in medical affairs costs in the amount of \$0.8 million during the three months ended June 30, 2021 compared to the three months ended June 30, 2020.
- **Net Loss:** For the second quarter of 2021, the Company had a net loss of \$22.0 million, or \$(0.85) per share, compared to

a net loss of \$15.5 million, or \$(0.66) 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 second 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 2278335. 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/6wc35srs>.

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 2278335.

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 ophthalmic diseases. Oyster Point Pharma's lead clinical program is focused on the development of OC-01 (varenicline) nasal spray, a highly selective cholinergic agonist, being developed as a preservative-free nasal spray to treat the signs and symptoms of dry eye disease and neurotrophic keratopathy. In December 2020, Oyster Point submitted to the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) 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 FDA. Oyster Point continues to expand its research and development pipeline through internal innovation and external collaborations, with a goal to bring transformative therapies to patients and the eye care providers who take care of them.

About OrbiMed

OrbiMed is a leading healthcare investment firm, with \$19 billion in assets under management. OrbiMed invests globally across the healthcare industry, from start-ups to large multinational corporations, through a range of private equity funds, public equity funds, and royalty/credit funds. OrbiMed seeks to be a capital provider of choice, providing tailored financing solutions and global team resources to help build world-class healthcare companies. OrbiMed's team of over 100 professionals is based in New York City, San Francisco, Shanghai, Hong Kong, Mumbai, Herzliya, and other key global markets.

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.¹ 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. OC-01 (varenicline) nasal spray has been shown to stimulate mucin secretion from conjunctival goblet cells in clinical studies and protein secretion from the lacrimal gland in preclinical animal models.

Varenicline is a partial nicotinic acetylcholine receptor agonist of $\alpha 4\beta 2$ and $\alpha 4\alpha 6\beta 2$ receptors, a moderate $\alpha 3\beta 4$ and $\alpha 3\alpha 5\beta 4$ receptor agonist, and a full $\alpha 7$ receptor agonist. Varenicline has been hypothesized to form a complex with an epitope of the Severe Acute Respiratory Syndrome-related Coronavirus 2 (SARS-CoV-2) spike protein that may block binding to receptors important for cellular entry, resulting in the prevention of viral entry into tissues¹. The administration of a nasal spray formulation of varenicline provides a high localized dose directly to the nasal mucosa, a frequent site of virus entry, replication and infection. Varenicline has been shown to inhibit viral entry and disrupt replication of SARS-CoV-2-alpha in an in vivo model and has been shown to have potent antiviral activity to SARS-CoV-2, SARS-CoV-2-alpha, and SARS-CoV-2-beta in in vitro assays.

The Prescription Drug User Fee Act (PDUFA) target action date for OC-01 (varenicline) nasal spray in dry eye disease is October 17, 2021, with a planned U.S. launch of OC-01 (varenicline) nasal spray in this indication in the fourth quarter of 2021, if approved by the FDA. 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 been established.

About OC-02 (simpinicline) Nasal Spray

OC-02 (simpinicline) nasal spray is a highly selective cholinergic agonist. Simpinicline is a strong nicotinic acetylcholine receptor agonist of activity at the $\alpha 4\beta 2$, $\alpha 3\beta 4$, $\alpha 3\alpha 5\beta 4$, and $\alpha 4\alpha 6\beta 2$ receptors and weak agonist activity at the $\alpha 7$ receptor. OC-02 has been previously studied in two Phase 2b clinical trials for dry eye disease.

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 rare disease characterized by decreased corneal sensitivity and poor corneal healing. The most common causes of corneal sensation loss are viral infection (herpes simplex virus and herpes zoster keratoconjunctivitis), followed by chemical burns, physical injuries, and ocular surface 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, NK can lead to vision loss and a breakdown of corneal integrity, potentially leading to cornea transplantation.

About Enriched Tear Film (ETF™) Gene Therapy

ETF™ Gene Therapy is a proprietary, investigational adeno-associated virus (AAV) based gene therapy approach where a target gene is delivered to human lacrimal gland cells via intralacrimal gland injection. Rather than replacing a gene that is defective or missing, a new gene is delivered that potentially may produce a selected naturally occurring protein, enzyme, or other therapeutic gene product. The goal for this target gene is to produce a gene product to change cell behavior and function on the ocular surface. The human lacrimal gland is a seromucous gland that secretes over 1,500 proteins and multiple classes of mucins into the tear film that help protect and nourish the ocular surface. It has been shown that when an ocular surface stress occurs, the lacrimal gland responds by up-regulating the production of proteins which are then secreted into the tear film in order to heal the ocular surface. The ETF™ Gene Therapy approach intends to leverage this same concept for ocular surface diseases by delivering a target gene to the lacrimal gland to direct the production of the selected gene product that may be secreted in the tear film and then delivered to the ocular surface. In addition, OC-01 (varenicline) nasal spray may play a role in ocular surface diseases treated with ETF™ Gene Therapy through its potential to modulate the secretion of a selected gene product. In ocular surface diseases with inadequate tear film production (such as neurotrophic keratopathy [NK]) and diseases where increased amounts of the selected gene product (such as a protein or enzyme) are required, cholinergic activation of the parasympathetic nervous system with OC-01 (varenicline) nasal spray has the potential to modulate the concentration of the selected gene product.

About Bacteriophage Therapy

Bacteriophages, also known as phages, are viruses that are found in the natural environment that infect and replicate specifically in bacteria. Once a bacteriophage attaches to a susceptible bacterium it causes the host cell to die, releasing new bacteriophage to infect other bacteria. Phages can have activity against both treatable and antibiotic-resistant bacteria. Bacteriophage have been used as antibacterial therapy since shortly after they were discovered in the early 20th century and have been previously used to treat diseases of the ocular surface in humans².

About the SARS-CoV-2 Virus

The Severe Acute Respiratory Syndrome-related Coronavirus 2 (SARS-CoV-2) is the virus responsible for coronavirus disease 2019 (COVID-19). This virus is from the Coronaviridae family that are broadly distributed among humans, other mammals, and birds. SARS-CoV-2 is a positive-sense single-stranded RNA virus.

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 Oyster Point Pharma (the “Company” or “our”) regarding the future of the Company’s business, our future plans and strategies, regulatory approvals, preclinical and 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 plans and objectives of management for future operations, future results of operations and financial position, business strategy, product candidates, regulatory approvals, planned future product commercialization, planned preclinical studies and clinical trials, expected results of preclinical studies or clinical trials, and their timing and likelihood of success, expected research and development commercialization costs, 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 OC-01, OC-02 and other product candidates in the US and Greater China; the beneficial characteristics, safety, efficacy and therapeutic effects of OC-01, OC-02 and our preclinical product candidates; plans relating to the further development, manufacturing and potential commercialization of Company product candidates in the US and in other countries, including potential additional indications or disease areas to be evaluated and pursued; the timing of initiation of our future preclinical studies or clinical trials; the uncertainties inherent in pharmaceutical research and development, including preclinical study and clinical trial results and additional analysis of existing data; the likelihood of clinical trials demonstrating safety and efficacy of our product candidates, and other positive results; our plans and potential for success relating to commercializing OC-01 and OC-02 in the US and Greater China; the prevalence of dry eye disease and Neurotrophic Keratopathy (NK) and the size of the market opportunities for our product candidates in the US and Greater China; our plans and ability to obtain or protect intellectual property rights in the US and Greater China, including extensions of existing patent terms where available; our ability to recruit and retain key personnel needed to develop and commercialize our product candidates, if approved, and to grow our company; the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise in the US and in other countries; existing regulations and regulatory developments in the United States, Greater China and other jurisdictions; our continued reliance on third parties to conduct additional preclinical studies and clinical trials of our product candidates, and for the manufacture of our product candidates for potential commercialization and for preclinical studies and clinical trials; the impact of the COVID-19 pandemic on our business, operations, and regulatory and clinical development timelines; 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.

1. Alexandris, N., Lagoumintzis, G., Chasapis, C. T., Leonidas, D. D., Papadopoulos, G. E., Tzartos, S. J., ... & Farsalinos, K. (2021). Nicotinic cholinergic system and COVID-19: In silico evaluation of nicotinic acetylcholine receptor agonists as potential therapeutic interventions. *Toxicology reports*, 8, 73-83.
2. Fadlallah, A., Chelala, E., & Legeais, J. M. (2015). Corneal infection therapy with topical bacteriophage administration. *The open ophthalmology journal*, 9, 167.

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Oyster Point Pharma, Inc.**Select Balance Sheet Data**

(in thousands)
 (unaudited)

	<u>June 30, 2021</u>		<u>December 31, 2020</u>	
Cash and cash equivalents	\$	154,805	\$	192,585
Working capital*	\$	149,415	\$	185,385
Total assets	\$	161,503	\$	197,910
Stockholders' equity	\$	151,784	\$	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)
 (unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Research and development:				
Clinical, preclinical	\$ 2,066	\$ 1,881	\$ 4,001	\$ 7,993
Chemistry, manufacturing and controls	3,420	5,723	9,045	9,560
Other	1,244	950	(488)	2,341
Total research and development	<u>6,730</u>	<u>8,554</u>	<u>12,558</u>	<u>19,894</u>
Selling, general and administrative	<u>15,296</u>	<u>6,940</u>	<u>28,388</u>	<u>12,529</u>
Loss from operations	<u>(22,026)</u>	<u>(15,494)</u>	<u>(40,946)</u>	<u>(32,423)</u>
Other income, net	<u>10</u>	<u>30</u>	<u>21</u>	<u>440</u>
Net loss and comprehensive loss	<u>\$ (22,016)</u>	<u>\$ (15,464)</u>	<u>\$ (40,925)</u>	<u>\$ (31,983)</u>
Net loss per share, basic and diluted	<u>\$ (0.85)</u>	<u>\$ (0.66)</u>	<u>\$ (1.58)</u>	<u>\$ (1.43)</u>
Weighted average shares outstanding, basic and diluted	<u>25,989,913</u>	<u>23,442,530</u>	<u>25,957,186</u>	<u>22,405,031</u>