

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-39112

**OYSTER POINT PHARMA, INC.**

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

202 Carnegie Center, Suite 109 Princeton, New Jersey  
(Address of principal executive offices)

81-1030955

(I.R.S. Employer  
Identification No.)

08540

(Zip Code)

Registrant's telephone number, including area code: (609) 382-9032

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001	OYST	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of April 30, 2021, the registrant had 25,977,778 shares of common stock, \$0.001 par value per share, outstanding.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Any statements contained in this Form 10-Q that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, such forward-looking statements are identified by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the likelihood of the Company's clinical trials demonstrating safety and efficacy of its product candidates, and other positive results;
- the timing of initiation of the Company's future clinical trials, and the reporting of data from completed, current and future clinical trials and preclinical studies;
- plans relating to the clinical development of the Company's product candidates, including the size, number and disease areas to be evaluated;
- the size of the market opportunity and prevalence of dry eye disease for the Company's product candidates;
- plans relating to commercializing the Company's 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 Company's estimates of the number of patients in the United States who suffer from dry eye disease and the number of patients that will enroll in its clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of the Company's product candidates;
- the timing, likelihood or scope of regulatory filings and approval for its product candidates;
- the Company's ability to obtain and maintain regulatory approval of its product candidates;
- the Company's plans relating to the further development and manufacturing of its product candidates, including additional indications for which it may pursue;
- 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, including extensions of existing patent terms where available;
- continued reliance on third parties to conduct additional clinical trials of the Company's product candidates, and for the manufacture and supply of product candidates, components for preclinical studies and clinical trials and products and components for commercialization of any approved products;
- the need to hire additional personnel, and the Company's ability to attract and retain such personnel;
- the potential effects of the novel strain coronavirus, or SARS-CoV-2 virus pandemic, on business, operations and clinical development timelines and plans;

- the accuracy of estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the Company's financial performance;
- the sufficiency of existing capital resources to fund future operating expenses and capital expenditure requirements;
- expectations regarding the period during which the Company will qualify as an emerging growth company under the JOBS Act; and
- the Company's anticipated use of its existing resources and proceeds from the initial and follow-on public offering.

The Company has based these forward-looking statements largely on its current expectations and projections about its business, the industry in which it operates and financial trends that may affect business, financial condition, results of operations and growth prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q, as well as Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2020. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, they should not be relied on as predictions of future events. The events and circumstances reflected in these forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, the Company does not plan to publicly update or revise any forward-looking statements after the date of this Quarterly Report on Form 10-Q, whether as a result of any new information, future events or otherwise.

In addition, statements that "the Company believes" and similar statements reflect the Company's beliefs and opinions on the relevant subject. These statements are based upon information available to the Company as of the date of this Quarterly Report on Form 10-Q, and while the Company believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and the Company's statements should not be read to indicate that it has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and should not be unduly relied upon.

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**PART I — FINANCIAL INFORMATION**  
**ITEM 1 — FINANCIAL STATEMENTS**  
**OYSTER POINT PHARMA, INC.**  
**CONDENSED BALANCE SHEETS**  
(in thousands, except share and per share amounts)  
(unaudited)

	March 31, 2021	December 31, 2020
<b>ASSETS</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 175,910	\$ 192,585
Prepaid expenses and other current assets	6,738	3,782
<b>Total current assets</b>	<b>182,648</b>	<b>196,367</b>
Property and equipment, net	1,121	804
Restricted cash	61	61
Other assets	30	—
Right-of-use assets, net	912	678
<b>Total Assets</b>	<b>\$ 184,772</b>	<b>\$ 197,910</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 7,093	\$ 2,279
Accrued expenses and other current liabilities	6,110	8,285
Lease liabilities	533	418
<b>Total current liabilities</b>	<b>13,736</b>	<b>10,982</b>
Lease liabilities, non-current	388	269
<b>Total Liabilities</b>	<b>14,124</b>	<b>11,251</b>
<b>Commitments and Contingencies (Note 7)</b>		
<b>Stockholders' Equity</b>		
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized; none outstanding	—	—
Common stock, \$0.001 par value per share; 1,000,000,000 shares authorized, 25,960,788 and 25,890,490 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	26	26
Additional paid-in capital	344,282	341,384
Accumulated deficit	(173,660)	(154,751)
<b>Total Stockholders' Equity</b>	<b>170,648</b>	<b>186,659</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 184,772</b>	<b>\$ 197,910</b>

The accompanying notes are an integral part of these condensed financial statements.

**OYSTER POINT PHARMA, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(in thousands, except share and per share amounts)**  
**(unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Operating expenses:</b>		
Research and development	\$ 5,828	\$ 11,340
Selling, general and administrative	13,092	5,589
Total operating expenses	18,920	16,929
<b>Loss from operations</b>	(18,920)	(16,929)
Other income, net	11	410
<b>Net loss and comprehensive loss</b>	\$ (18,909)	\$ (16,519)
<b>Net loss per share, basic and diluted</b>	\$ (0.73)	\$ (0.77)
<b>Weighted average shares outstanding, basic and diluted</b>	25,924,096	21,367,532

The accompanying notes are an integral part of these condensed financial statements.

**OYSTER POINT PHARMA, INC.**  
**CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands, except share amounts)  
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balance at January 1, 2021</b>	25,890,490	\$ 26	\$ 341,384	\$ (154,751)	\$ 186,659
Net loss	—	—	—	(18,909)	(18,909)
Issuance of common stock upon exercise of stock options	55,046	—	218	—	218
Issuance of common stock upon vesting of restricted stock units	15,252	—	—	—	—
Stock-based compensation expense	—	—	2,680	—	2,680
<b>Balance at March 31, 2021</b>	<u>25,960,788</u>	<u>\$ 26</u>	<u>\$ 344,282</u>	<u>\$ (173,660)</u>	<u>\$ 170,648</u>

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balance at January 1, 2020</b>	21,366,950	\$ 21	\$ 221,508	\$ (84,231)	\$ 137,298
Net loss	—	—	—	(16,519)	(16,519)
Issuance of common stock upon exercise of stock options	3,530	—	4	—	4
Stock-based compensation expense	—	—	1,180	—	1,180
<b>Balance at March 31, 2020</b>	<u>21,370,480</u>	<u>\$ 21</u>	<u>\$ 222,692</u>	<u>\$ (100,750)</u>	<u>\$ 121,963</u>

The accompanying notes are an integral part of these condensed financial statements.

**OYSTER POINT PHARMA, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
(in thousands)  
(unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (18,909)	\$ (16,519)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,680	1,180
Depreciation	23	17
Reduction in the carrying amount of the right-of-use assets	110	92
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(2,949)	645
Accounts payable	4,812	6,384
Change in lease liabilities	(109)	(93)
Accrued expenses and other current liabilities	(2,158)	(2,118)
Other assets	(30)	—
Net cash used in operating activities	<u>(16,530)</u>	<u>(10,412)</u>
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(340)	(99)
Net cash used in investing activities	<u>(340)</u>	<u>(99)</u>
<b>Cash flows from financing activities</b>		
Payment of deferred offering costs	(23)	—
Proceeds from the exercise of stock options	218	4
Net cash provided by financing activities	<u>195</u>	<u>4</u>
Net decrease in cash, cash equivalents and restricted cash	<u>(16,675)</u>	<u>(10,507)</u>
<b>Cash, cash equivalents and restricted cash at the beginning of the period</b>	<u>192,646</u>	<u>139,198</u>
<b>Cash, cash equivalents and restricted cash at the end of the period</b>	<u>\$ 175,971</u>	<u>\$ 128,691</u>
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	\$ 175,910	\$ 128,630
Restricted cash	61	61
Cash, cash equivalents and restricted cash	<u>\$ 175,971</u>	<u>\$ 128,691</u>
Supplemental cash flow information		
Right-of-use for office space and office equipment acquired through leases	\$ 344	\$ 320

The accompanying notes are an integral part of these condensed financial statements.

**OYSTER POINT PHARMA, INC.**  
**Notes to Unaudited Interim Condensed Financial Statements**

**1. Nature of Business, Basis of Presentation and Significant Accounting Policies**

*Description of the Business*

Oyster Point Pharma, Inc. (the Company) is a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of pharmaceutical therapies to treat ocular surface diseases. The Company's principal office is located in Princeton, New Jersey. From inception through March 31, 2021, the Company has been engaged in business planning, research, clinical development of its therapeutic product candidates, recruiting and raising capital.

*Liquidity*

The Company incurred net losses of \$18.9 million and \$16.5 million for the three months ended March 31, 2021 and 2020, respectively, and had an accumulated deficit of \$173.7 million as of March 31, 2021. The Company expects to incur an increase in expense related to the Company's preparation for the commercialization of its lead product candidate, OC-01 (varenicline) nasal spray, if approved by the U.S. Food and Drug Administration (FDA), including to establish commercial scale manufacturing arrangements and to provide for the marketing, commercial operations and distribution of the product. The Company expended and will continue to expend additional funds to complete the research, development and clinical testing of its product candidates. The Company will require additional funds to commercialize its products. The Company is unable to entirely fund these efforts with its current financial resources and there can be no assurance that it will be able to secure such additional financing on a timely basis, if at all, that will be sufficient to meet these needs. If adequate funds are unavailable on a timely basis from operations or additional sources of financing, the Company may have to delay, reduce and or eliminate certain commercial related expenses, included in selling, general and administrative expenses, as well as delay, reduce and or eliminate the scope of one or more of its research or development programs, which would materially and adversely affect its business, financial condition and operations.

The Company is subject to risks and uncertainties as a result of the SARS-CoV-2 virus pandemic. The pandemic and any related public health developments, have adversely affected workforces, economies, and financial markets globally, potentially leading to an economic downturn. It is not possible for the Company to predict the duration or magnitude of the adverse results of the pandemic or the full extent of its effects on the Company's financial condition, liquidity or results of operations.

The Company had cash and cash equivalents of \$175.9 million as of March 31, 2021. Management believes that the Company's current cash and cash equivalents will be sufficient to fund its planned operations for at least 12 months from the date of issuance of these financial statements.

*Basis of Presentation*

The unaudited interim condensed financial statements and accompanying notes have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the accompanying unaudited condensed financial statements contain all adjustments, which are of a normal recurring nature, necessary to state fairly the Company's financial position as of March 31, 2021 and as of December 31, 2020, the results of operations for the three months ended March 31, 2021 and 2020, and cash flows for the three months ended March 31, 2021 and 2020. While management believes that the disclosures presented are adequate to mitigate the risk of the information being misleading, these unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. The results of the Company's operations for any interim period are not necessarily indicative of the results of operations for any other interim period or for the full year.

### *Use of Estimates*

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of expenses in the condensed financial statements and accompanying notes. Significant items subject to such estimates and assumptions include stock-based compensation and certain research and development accruals. Actual results could differ from these estimates, and such differences could be material to the Company's financial position and results of operations.

### *Summary of Significant Accounting Policies*

The Company's significant accounting policies are disclosed in Note 1. *Nature of Business, Basis of Presentation and Significant Accounting Policies* in the Annual Report on Form 10-K for the year ended December 31, 2020. There have been no material changes in the Company's accounting policies from those disclosed in the financial statements and the related notes included in the Annual Report on Form 10-K for the year ended December 31, 2020.

### *Recent Accounting Pronouncements*

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the FASB) under its accounting standard codifications (ASC) or other standard setting bodies and are adopted by the Company as of the specified effective date, unless otherwise discussed below.

*ASU 2020-10* — In October 2020, the FASB issued ASU 2020-10, Codification Improvements, which updated various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The amendments in ASU 2020-10 are effective for annual periods beginning after December 15, 2020, for public business entities. The Company adopted ASU 2020-10 on January 1, 2021 and its adoption did not have a material effect on the Company's financial statements and related disclosures.

### *Reclassification*

Certain prior year amounts have been reclassified for comparative purposes.

## **2. Fair Value Measurements**

The Company assesses the fair value of financial instruments as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of March 31, 2021, financial assets measured and recognized at fair value on a recurring basis were as follows (in thousands):

**OYSTER POINT PHARMA, INC.**  
**Notes to Unaudited Interim Condensed Financial Statements (continued)**

	Fair Value Measurements at March 31, 2021			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
<b>Assets</b>				
Money market funds	\$ 174,910	\$ —	\$ —	\$ 174,910
Total fair value of assets	\$ 174,910	\$ —	\$ —	\$ 174,910

As of December 31, 2020, financial assets measured and recognized at fair value on a recurring basis were as follows (in thousands):

	Fair Value Measurements at December 31, 2020			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
<b>Assets</b>				
Money market funds	\$ 191,585	\$ —	\$ —	\$ 191,585
Total fair value of assets	\$ 191,585	\$ —	\$ —	\$ 191,585

Money market funds are included in cash and cash equivalents on the Company's condensed balance sheets and are classified within Level 1 of the fair value hierarchy as they are valued using quoted market prices.

The carrying amounts reflected in the Company's condensed balance sheets for cash equivalents, prepaid expenses and other current assets, restricted cash, accounts payable and accrued expenses and other liabilities approximate their fair values, due to their short-term nature.

*Concentration of Credit Risk*

Financial instruments that potentially subject the Company to concentrations of credit risk are money market funds, which are included in cash and cash equivalents on the Company's condensed balance sheets. The Company attempts to minimize the risks related to cash and cash equivalents by using highly-rated financial institutions that invest in a broad and diverse range of financial instruments. The Company's investment portfolio is maintained in accordance with its investment policy that defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer.

**3. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Accrued compensation	\$ 2,081	\$ 3,500
Accrued professional services	2,078	1,244
Accrued research and development expense	1,951	3,541
Total accrued expenses and other current liabilities	\$ 6,110	\$ 8,285

#### 4. Stockholders' Equity

##### Common Stock

The Company is authorized to issue 1,000,000,000 shares of common stock, at a par value of \$0.001 per share. Each share of common stock is entitled to one vote.

The Company reserved common stock for future issuance as follows:

	March 31, 2021	December 31, 2020
Outstanding options under the 2016 Equity Incentive Plan	2,487,560	2,567,566
Outstanding options under the 2019 Equity Incentive Plan	1,545,484	918,145
Equity awards available for grant under the 2019 Plan <sup>(1)</sup>	2,128,714	1,790,106
Unvested restricted stock units (RSUs)	140,595	61,215
Shares reserved for purchase under the ESPP	270,000	270,000
<b>Total</b>	<b>6,572,353</b>	<b>5,607,032</b>

<sup>(1)</sup> — Effective January 1, 2021, in connection with the evergreen provision under the 2019 Equity Incentive Plan (the 2019 Plan) 1,035,619 shares were added to the 2019 Plan.

##### Stock Options

The following table summarizes stock option activity under the 2016 Equity Incentive Plan and the 2019 Plan during the three months ended March 31, 2021 (in thousands, except share, contractual term and per share data):

	Outstanding Options			
	Number of Shares Underlying Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
<b>Balance, January 1, 2021</b>	3,485,711	\$ 10.74	8.2	\$ 36,506
Options granted	669,466	18.87		
Options exercised	(55,046)	3.95		925
Options forfeited	(67,087)	16.27		335
<b>Balance, March 31, 2021</b>	<b>4,033,044</b>	<b>12.09</b>	<b>8.2</b>	<b>34,041</b>
<b>Shares vested and exercisable as of March 31, 2021</b>	<b>1,788,572</b>	<b>5.93</b>	<b>7.4</b>	<b>24,180</b>
<b>Vested and expected to vest as of March 31, 2021</b>	<b>4,033,044</b>	<b>\$ 12.09</b>	<b>8.2</b>	<b>\$ 34,041</b>

The weighted average fair value of options granted during the three months ended March 31, 2021 was \$11.68 per share. As of March 31, 2021, the total unrecognized stock-based compensation expense for stock options was \$26.5 million, which is expected to be recognized over a weighted average period of 3.1 years.

##### Restricted Stock Units

Restricted stock units (RSUs) are granted to the Company's directors and employees. The value of an RSU award is based on the Company's stock price on the date of the grant. The shares underlying the RSUs are not issued until the RSUs vest. Upon vesting, each RSU converts into one share of the Company's common stock.

Activity with respect to the Company's restricted stock units during the three months ended March 31, 2021 was as follows (in thousands, except share, contractual term, and per share data):

**OYSTER POINT PHARMA, INC.**  
**Notes to Unaudited Interim Condensed Financial Statements (continued)**

	Outstanding RSUs			
	Number of Shares Underlying Outstanding Awards	Weighted Average Grant Date Fair Value per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
<b>Outstanding at January 1, 2021</b>	61,215	\$ 23.83	1.4	\$ 1,152
Restricted stock units granted	95,004	18.77		1,783
Restricted stock units vested	(15,252)	27.61		328
Restricted units forfeited	(372)	18.77		8
<b>Balance, March 31, 2021</b>	140,595	20.02	7.1	2,570
<b>Unvested and expected to vest as of March 31, 2021</b>	140,595	\$ 20.02	7.1	\$ 2,570

As of March 31, 2021, the total unrecognized stock-based compensation expense for RSUs was \$2.5 million, which is expected to be recognized over a weighted average period of 3.0 years.

*Stock-Based Compensation Expense*

Total stock-based compensation expense recorded related to awards granted to employees and non-employees was as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ 366	\$ 217
Selling, general and administrative	2,314	963
Total stock-based compensation expense	\$ 2,680	\$ 1,180

**5. Net Loss Per Share**

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
Numerator:		
Net loss	\$ (18,909)	\$ (16,519)
Denominator:		
Weighted average shares outstanding, basic and diluted	25,924,096	21,367,532
Net loss per share, basic and diluted	\$ (0.73)	\$ (0.77)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	<b>As of March 31,</b>	
	<b>2021</b>	<b>2020</b>
Options to purchase common stock	4,033,044	3,261,499
Unvested restricted stock units	140,595	23,125
Total	4,173,639	3,284,624

**6. Leases**

The Company is party to several operating and finance lease agreements related to office and laboratory space and office equipment.

In February 2021, the Company entered into a lease agreement for laboratory and office space in New Jersey for a three-year term beginning on March 1, 2021 and ending on February 29, 2024. Total future minimum lease payments under the Company's lease agreements are \$0.9 million as of March 31, 2021.

Supplemental balance sheet information for the Company's leases is as follows (in thousands):

	<b>March 31, 2021</b>	<b>December 31, 2020</b>
Operating lease right-of-use asset	\$ 882	\$ 644
Finance lease right-of-use asset	30	34
<b>Total right-of-use asset</b>	<b>\$ 912</b>	<b>\$ 678</b>
Operating lease liabilities	\$ 515	\$ 400
Finance lease liabilities	18	18
<b>Total lease liabilities</b>	<b>\$ 533</b>	<b>\$ 418</b>
Operating lease liabilities, non-current	\$ 373	\$ 250
Finance lease liabilities, non-current	15	19
<b>Total lease liabilities, non-current</b>	<b>\$ 388</b>	<b>\$ 269</b>

The maturities of the lease liabilities under non-cancelable operating and finance leases are as follows (in thousands):

<b>As of March 31, 2021</b>	<b>Finance Leases</b>	<b>Operating Leases</b>	<b>Total</b>
2021 (remainder)	\$ 14	\$ 414	\$ 428
2022	16	376	392
2023	4	126	130
2024	—	21	21
<b>Total undiscounted cash flows</b>	<b>34</b>	<b>937</b>	<b>971</b>
Less: imputed interest	(1)	(49)	(50)
<b>Total lease liability</b>	<b>33</b>	<b>888</b>	<b>921</b>
Less: current portion	(18)	(515)	(533)
<b>Lease liability</b>	<b>\$ 15</b>	<b>\$ 373</b>	<b>\$ 388</b>

**7. Commitments and Contingencies**

*License Agreement*

The Company is party to a non-exclusive patent license agreement with Pfizer, which granted the Company non-exclusive rights under Pfizer's patent rights covering varenicline tartrate to develop, manufacture, and commercialize the OC-01 (varenicline) nasal spray product. Under the terms of the agreement, the Company made an upfront payment to Pfizer of \$5 million during the year ended December 31, 2019. If the Company commercializes OC-01 (varenicline) nasal spray, it may be required to pay a single milestone payment in low double-digit millions and tiered royalties on net sales of OC-01 (varenicline) nasal spray at percentages ranging from the mid-single digits to the mid-teens. The royalty obligation to Pfizer would commence upon the first commercial sale of OC-01 (varenicline) nasal spray and expire upon the later of (a) the expiration of all regulatory or data exclusivity granted to Pfizer in connection with varenicline in the United States; and (b) the expiration or abandonment of

the last valid claims of the licensed patents. No milestone was achieved or probable to be achieved or royalties payable accrued as of March 31, 2021 and December 31, 2020.

*Contingencies*

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. There are no matters pending that the Company currently believes are reasonably possible or probable of having a material impact to the Company's business, financial position, results of operations, or statements of cash flows.

## **Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

The following discussion analyzes the Company's historical financial condition and results of operations. As you read this discussion and analysis, refer to the Company's financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q, which represents the results of operations for the three months ended March 31, 2021 and 2020. Also refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2020, which includes detailed discussions of various items impacting the Company's business, results of operations and financial condition. The discussion and analysis below has been organized as follows:

- Executive summary, including a description of the business and recent events that are important to understanding the results of operations and financial condition;
- Results of operations, including an explanation of significant differences between the periods in the specific line items of the condensed statements of operations;
- Financial condition addressing the Company's sources of liquidity, future funding requirements, cash flow, sources and uses of cash, updates to contractual obligations and commitments, and off-balance sheet arrangements; and
- Critical accounting policies, significant judgements and estimates, which are most important to both the portrayal of the Company's results of operations and financial condition.

Some of the information contained in the following discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to the Company's plans and strategy for its business, includes forward-looking statements within the meaning of Section 27A of the Act and Section 21E of the Exchange Act that involve risks and uncertainties. As a result of many factors, including those factors set forth in the “Risk Factors” section of the Company's Annual Report on Form 10-K for the year ended December 31, 2020 and in this Quarterly Report on Form 10-Q, the Company's actual results could differ materially from the results described in or implied by these forward-looking statements. Please also see the section of this Quarterly Report on Form 10-Q titled “Special Note Regarding Forward-Looking Statements.”

## Executive Summary

### Introduction and Overview

Oyster Point Pharma, Inc. is a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases. The Company's lead product candidate OC-01 (varenicline) nasal spray, a highly selective nicotinic acetylcholine receptor (nAChR) agonist, is being developed as a nasal spray to treat the signs and symptoms of dry eye disease. Based on OC-01 (varenicline) nasal spray's clinical trial results and its novel mechanism of action, the Company believes OC-01 (varenicline) nasal spray, if approved by the FDA, has the potential to become the new standard of care and redefine how dry eye disease is treated for millions of patients.

The Company has no products approved for sale and has not generated revenue since its inception in 2015. The Company expects to finance its operations through private and public equity or debt financing, collaborative or other arrangements with corporate sources or through other sources of financing. The Company's net losses were \$18.9 million and \$16.5 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, the Company had an accumulated deficit of \$173.7 million. The Company expects that its selling, general and administrative expenses will increase as the Company prepares for the commercialization of its lead product candidate, OC-01 (varenicline) nasal spray, if approved by the FDA. Additionally, operating expenses will increase as the Company advances its other product candidates through preclinical and clinical development, seeks regulatory approval, and prepares for and, if approved, proceeds to commercialization; acquires, discovers, validates and develops additional product candidates; obtains, maintains, protects and enforces its intellectual property portfolio; and hires additional personnel. In addition, the Company has incurred and will continue to incur additional costs associated with operating as a public company.

The Company plans to continue to use third-party service providers, including clinical research organizations (CROs) and contract manufacturing organization (CMOs), to carry out its preclinical and clinical development and to manufacture and supply the materials to be used during the development and commercialization of its product candidates. The Company does not currently have a sales force. If OC-01 (varenicline) nasal spray is approved, the Company intends to deploy a specialty sales force of approximately 150 to 200 field representatives targeting the top-prescribing ophthalmologists and optometrists in the United States.

### Recent Events

*Prescription Drug User Fee Act (PDUFA) target action date of October 17, 2021*

The Company submitted a 505(b)(2) New Drug Application (NDA) for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease in December 2020. The FDA has assigned a PDUFA target action date of October 17, 2021 as the goal to complete its review of the NDA.

*The Impact of the SARS-CoV-2 Virus Pandemic*

During the three months ended March 31, 2021, financial results of the Company were not significantly affected by the SARS-CoV-2 virus pandemic. However, the extent to which the SARS-CoV-2 virus pandemic may affect the Company's future financial results and operations will depend on future developments which are highly uncertain and cannot be predicted, including new information which may emerge concerning the pandemic, and current or future domestic and international actions to contain it and treat it. The Company continues to evaluate the impact of the SARS-CoV-2 virus pandemic on its trials, expected timelines and costs, as well as potential supply-chain challenges as it prepares itself for commercialization of the OC-01 (varenicline) nasal spray candidate and as it continues to learn more about the impact of the SARS-CoV-2 virus pandemic on the industry.

The Company continues to evaluate and develop pipeline candidates for the potential treatment of various medical indications. The ongoing SARS-CoV-2 virus pandemic may impact access to supplies necessary to conduct preclinical studies, cause delay to the timelines to initiate or complete *in vitro* or *in vivo* animal studies, or indirectly impact the operation of contract organizations that are necessary for the Company to advance preclinical projects. If the SARS-CoV-2 virus pandemic continues and persists for an extended period of time, the Company could experience significant disruptions to its clinical development timelines, which could adversely affect its business, financial condition and results of operations.

For further discussion of the risks that the Company faces as a result of the SARS-CoV-2 virus pandemic refer to the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

## Results of Operations

### Comparison of the Results of Operations for the Three Months Ended March 31, 2021 and 2020

The following table summarizes the Company's results of operations for the periods indicated (in thousands, except percentages):

	Three Months Ended March 31,		\$ Change	% Change
	2021	2020		
Research and development:				
Clinical, preclinical	\$ 1,935	\$ 6,112	\$ (4,177)	(68)%
Chemistry, manufacturing and controls (CMC)	5,625	3,837	1,788	47 %
Other	(1,732)	1,391	(3,123)	(225)%
Total research and development	5,828	11,340	(5,512)	(49)%
Selling, general and administrative	13,092	5,589	7,503	134 %
Loss from operations	(18,920)	(16,929)	(1,991)	12 %
Other income, net	11	410	(399)	(97)%
Net loss	\$ (18,909)	\$ (16,519)	\$ (2,390)	14 %

#### Research and Development 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, preclinical expense was \$4.2 million lower during the first quarter of 2021 as compared to the first quarter of 2020 primarily due to the completion of the ONSET-2 Phase 3 clinical trial in May 2020. The Company's CMC expense increased \$1.8 million primarily due to the continued advancement of OC-01 (varenicline) nasal spray and expenses incurred in connection with the anticipated commercial launch of OC-01 (varenicline) nasal spray, if approved by the FDA.

In December 2020, the Company paid a fee of \$2.9 million to the FDA under the Prescription Drug User Fee Act (PDUFA) in conjunction with the filing of its NDA for OC-01(varenicline) nasal spray. The Company filed a request with the FDA to grant a waiver and refund of the fee under the small business waiver provision of the PDUFA. Due to the uncertainty regarding the collectability of this refund, the Company recorded the filing fee in research and development expense in December 2020. In February 2021, the FDA granted the Company's request for the waiver. The refund was recorded as a gain in other research and development expense for the three months ended March 31, 2021. The FDA refunded the application fee in April 2021.

#### Selling, General and Administrative 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.

#### Other Income, Net

Other income, net decreased by \$0.4 million for the three months ended March 31, 2021 compared to the three months ended March 31, 2020, primarily due to lower rate of return on the money market funds earned during the period.

## **Liquidity and Capital Resources**

### *Sources of Liquidity*

As of March 31, 2021 and December 31, 2020, the Company had cash and cash equivalents of \$175.9 million and \$192.6 million, respectively.

### *Future Funding Requirements*

Based on the current business plan, management believes that its available cash and cash equivalents will be sufficient to fund the Company's planned operations for at least 12 months from the filing date of this Quarterly Report on Form 10-Q.

On December 17, 2020, the Company submitted a 505(b)(2) NDA to the FDA for its first lead product candidate, OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease. The Company expects to incur an increase in expense related to the Company's preparation for the commercialization of OC-01 (varenicline) nasal spray, if approved, including expenses for the establishment of commercial scale manufacturing arrangements, and to prepare for market access, marketing, distribution and commercial operations. In addition, the Company will continue to expend funds to initiate, continue and or complete the research, development and clinical testing of its current and future product candidates.

Since inception, the Company has incurred recurring losses and negative cash flows from operations. The Company generated net losses of \$18.9 million and \$16.5 million for the three months ended March 31, 2021 and 2020, respectively, and had an accumulated deficit of \$173.7 million as of March 31, 2021. The Company has historically financed its operations primarily through the sale and issuance of its securities. The Company does not expect to generate any meaningful revenue unless and until it obtains regulatory approval of and commercializes any of its product candidates or decides to enter into collaborative agreements with third parties. The Company is subject to all of the risks typically related to the development of new product candidates, and it may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. The Company will require additional funds to commercialize its products and fund operations for the foreseeable future. The Company is unable to entirely fund these efforts with its current financial resources and there can be no assurance that it will be able to secure such additional financing on a timely basis, if at all, that will be sufficient to meet these needs. If adequate funds are unavailable on a timely basis from operations or additional sources of financing, the Company may have to delay, reduce and or eliminate certain commercial related expenses, included in selling, general and administrative expenses, as well as delay, reduce and or eliminate the scope of or eliminate one or more of its research or development programs, which would materially and adversely affect its business, financial condition and operations. The Company may seek to raise capital through private or public equity or debt financings, collaborative or other arrangement with corporate sources, or through other sources of financing.

The Company anticipates that it will need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of the Company's drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for the Company's product candidates;
- the number and scope of clinical programs the Company decides to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of the Company's product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing of the Company's product candidates, if they receive marketing approval;
- the extent to which the Company acquires or in-licenses other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing the Company's intellectual property rights and defending intellectual property-related claims;
- the Company's ability to establish and maintain collaborations on favorable terms, if at all;
- its efforts to enhance operational systems and the Company's ability to attract, hire and retain qualified personnel, including personnel to support the development of the Company's product candidates and, ultimately, the sale of the Company's products, following FDA approval;
- the Company's implementation of operational, financial and management systems;

- any current or future potential effects of the SARS-CoV-2 virus pandemic on the Company's business, operations, preclinical and clinical development and commercialization timelines and plans; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of the Company's product candidates could significantly change the costs and timing associated with the development of that product candidate.

Furthermore, the Company's operating plans may change in the future, and it will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If additional funds are raised by issuing equity securities, the Company's stockholders may experience dilution. Any future debt financing into which the Company might enter may impose upon it additional covenants that restrict the Company's operations, including limitations on its ability to incur liens or additional debt, pay dividends, repurchase its common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that it raises may contain terms that are not favorable to the Company or its stockholders.

Adequate funding may not be available to the Company on acceptable terms or at all, and any uncertainty and volatility in capital markets caused by the SARS-CoV-2 virus pandemic may negatively impact the availability and cost of capital. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce, or terminate some or all of its development programs and clinical trials or may also be required to sell or license to others rights to its product candidates in certain territories or indications that it would prefer to develop and commercialize itself. If the Company is required to enter into collaborations and other arrangements to supplement its funds, it may have to give up certain rights that limit its ability to develop and commercialize the product candidates or may have other terms that are not favorable to the Company or its stockholders, which could materially affect its business, results of operation and financial condition.

See Item 1A. Risk Factors to the Annual Report on Form 10-K for the year ended December 31, 2020 for additional risks associated with the Company's substantial capital requirements.

#### Cash Flow Discussion

The following table sets forth the primary sources and uses of cash, cash equivalents and restricted cash for each of the periods presented below (in thousands):

	<b>Three Months Ended March 31,</b>		<b>\$ Change</b>
	<b>2021</b>	<b>2020</b>	
Net cash (used in) provided by:			
Operating activities	\$ (16,530)	\$ (10,412)	\$ (6,118)
Investing activities	(340)	(99)	(241)
Financing activities	195	4	191
Net decrease in cash and cash equivalents	<u>\$ (16,675)</u>	<u>\$ (10,507)</u>	<u>\$ (6,168)</u>

#### *Cash Flows Used in Operating Activities*

Net cash used in operating activities increased by \$6.1 million for the three months ended March 31, 2021 compared to the three months ended March 31, 2020, due to higher net loss adjusted for non-cash items during the period, as well as a decrease in working capital of \$5.2 million driven primarily by the timing of payments to the Company's service providers. The Company's higher net loss was driven by the continued development of the Company's product candidates and preparation for the commercial launch of the Company's main product candidate, OC-01 (varenicline) nasal spray, if approved, in the fourth quarter of 2021.

#### *Cash Flows Used in Investing Activities*

Net cash used in investing activities increased by \$0.2 million for the three months ended March 31, 2021 compared to the three months ended March 31, 2020, primarily related to partial payments for equipment to be used in manufacturing of OC-01 (varenicline) nasal spray.

### *Cash Flows Provided by Financing Activities*

Net cash provided by financing activities increased by \$0.2 million for the three months ended March 31, 2021 compared to the three months ended March 31, 2020, primarily due to an increase in the proceeds received from the exercise of stock options during the three months ended March 31, 2021.

### **Contractual Obligations and Commitments**

In February 2021, the Company entered into a lease agreement for laboratory and office space in New Jersey for a three-year term beginning on March 1, 2021 and ending on February 29, 2024. Total future minimum lease payments under this agreement are \$0.4 million.

As of March 31, 2021, there have been no other material changes in the contractual obligations and commitments from those disclosed in the financial statements and the related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

### **Off-Balance Sheet Arrangements**

As of March 31, 2021, the Company does not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### **Critical Accounting Policies, Significant Judgments and Estimates**

The Company's financial statements have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses incurred during the reporting periods. The Company bases its estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The future effects of the SARS-CoV-2 virus pandemic on the Company's results of operations, cash flows, and financial position are unclear, however the Company believes it has used reasonable estimates and assumptions in preparing the interim condensed financial statements. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to the Company's critical accounting policies and estimates from the information provided in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

### **Recent Accounting Pronouncements**

See "Recent Accounting Pronouncements" in *Note 1. Nature of Business, Basis of Presentation and Significant Accounting Policies* to the Company's unaudited interim condensed financial statements included in this Quarterly Report.

### *JOBS Act*

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this extended transition period, and, as a result, it will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. The Company intends to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

The Company will remain an emerging growth company until the earliest to occur of: (1) the last day of its first fiscal year in which it has total annual revenues of more than \$1.07 billion; (2) the date it qualifies as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates; (3) the date on which it has issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of its initial public offering.

### **ITEM 3 — Quantitative and Qualitative Disclosures about Market Risk**

#### *Interest Rate Sensitivity*

The market risk inherent in the Company's financial instruments and in its financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. As of March 31, 2021, the Company had cash equivalents of \$174.9 million, consisting of interest-bearing money market funds for which the fair value would be affected by changes in the general level of U.S. interest rates. However, due to the short-term maturities and the low-risk profile of cash equivalents, an immediate 10% relative change in interest rates would not have a material effect on the fair value of the Company's cash equivalents or on its future interest income.

The Company does not believe that inflation, interest rate changes or foreign currency exchange rate fluctuations have had a significant impact on its results of operations for any periods presented herein.

### **ITEM 4 — Controls and Procedures**

#### *Evaluation of Disclosure Controls and Procedures*

As of March 31, 2021, management, with the participation of the Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation of its disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of March 31, 2021 to provide reasonable assurance that information required to be disclosed in the Company's reports under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to the Company's management, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

#### *Changes in Internal Control over Financial Reporting*

There were no changes in the Company's internal control over financial reporting during the three months ended March 31, 2021 that have materially affected, or are reasonably likely to materially affect the Company's internal control over financial reporting.

## PART II — OTHER INFORMATION

### ITEM 1 — Legal Proceedings.

None.

### ITEM 1A — Risk Factors.

Information regarding risk factors appears in Part I, Item 1A, Risk Factors, in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. The Company has reviewed the risk factors, and, except as presented below, there have been no material changes in the Company's risk factors since those reported in its Annual Report on Form 10-K for the year ended December 31, 2020.

***If the FDA does not conclude that OC-01 (varenicline) nasal spray satisfies the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act (FFDCA), or if the requirements for such product candidates under Section 505(b)(2) are not as the Company expects, the approval pathway for those product candidates may take longer, cost more or entail greater complications and risks than anticipated, and may not be successful.***

The Company submitted an NDA for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease in December 2020, and the FDA has assigned a PDUFA target action date of October 17, 2021 as the goal to complete its review of the NDA. The Company is seeking FDA approval through the Section 505(b)(2) regulatory pathway for OC-01 (varenicline) nasal spray. Section 505(b)(2) of the FFDCA permits the submission of a New Drug Application (NDA) where some or all of the data required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Company's ability to rely on certain of the FDA's findings of safety and effectiveness in approval of another NDA or on studies published in the scientific literature will depend on its ability to demonstrate the relevance to OC-01 (varenicline) nasal spray.

In particular, the Company conducted ZEN, a comparative pharmacokinetic "bridge" trial, to evaluate the relative bioavailability of varenicline administered as a nasal spray (OC-01) compared to varenicline administered orally (Chantix®) in order to reference certain FDA conclusions regarding the safety of varenicline from the Agency's review of the Chantix NDA. If the FDA does not accept or disagrees with the Company's conclusions from ZEN or the data required for approval of its Section 505(b)(2) NDA are different than anticipated, the Company may be required to conduct additional development activities or studies or provide additional data and information to pursue the 505(b)(2) regulatory pathway on its proposed timeline. Such delays could result in new competitive products reaching the market faster than OC-01 (varenicline) nasal spray, which could materially adversely impact the Company's competitive position and growth prospects.

***The Company may face difficulties from changes to current regulations and future legislation.***

In the United States, the European Union and other jurisdictions there have been a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect the Company's future results of operations. Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of the product candidates. The Company cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If the Company is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if it is unable to maintain regulatory compliance, it may lose any marketing approval that may have been obtained and the Company may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (or collectively, the ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry.

The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including

increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits.

There have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed. On December 22, 2017, President Trump signed into law federal tax legislation commonly referred to as the Tax Cuts and Jobs Act (the Tax Act), which included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." The 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made or how the Supreme Court will rule. On February 10, 2021, President Biden withdrew the federal government's support for overturning the ACA. Although the United States Supreme Court has not yet ruled on the constitutionality of the ACA, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is also unclear how such litigation and other efforts to repeal and replace the ACA and the healthcare reform measures of the Biden administration will impact the ACA and the Company's business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. Legislation is currently pending in Congress that would further extend the suspension through December 31, 2021. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for the Company's product candidates, if approved, and accordingly, the financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, at the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA also released a final rule, on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The Implementation of the rule has been

delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. In addition, on November 20, 2020, the Centers for Medicare and Medicaid Services (CMS) issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The Company expects that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that the Company receives for any approved product. It is possible that additional governmental action is taken in response to address the SARS-CoV-2 virus pandemic. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent the Company from being able to generate revenue, attain profitability or commercialize its product candidates.

In the European Union, similar political, economic and regulatory developments may affect the Company's ability to profitably commercialize its product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase the Company's operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of the Company's product candidates, restrict or regulate post-approval activities and affect its ability to commercialize its product candidates, if approved.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. The Company cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, particularly in light of the recent presidential election, or what the impact of such changes on the marketing approvals of the Company's product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA approval process may significantly delay or prevent marketing approval, as well as subject the Company to more stringent product labeling and post-marketing testing and other requirements.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

Exhibit Number	Description	Form	File No.	Number	Filing Date
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	8-K	001-39112	3.1	November 5, 2019
3.2	<a href="#">Amended and Restated Bylaws</a>	8-K	001-39112	3.2	November 5, 2019
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
32.1*+	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				
32.2*+	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

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\* Filed herewith.

+ The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**OYSTER POINT PHARMA, INC.**

Date: May 6, 2021

By: \_\_\_\_\_  
/s/ Jeffrey Nau  
Jeffrey Nau, Ph.D., M.M.S.  
President, Chief Executive Officer and Director

Date: May 6, 2021

By: \_\_\_\_\_  
/s/ Daniel Lochner  
Daniel Lochner  
Chief Financial Officer

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jeffrey Nau, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oyster Point Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2021

By: /s/ Jeffrey Nau

Jeffrey Nau, Ph.D., M.M.S.

President and Chief Executive Officer

*(Principal Executive Officer)*

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Daniel Lochner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oyster Point Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2021

By: /s/ Daniel Lochner  
Daniel Lochner  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER**

**PURSUANT TO**

**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Oyster Point Pharma, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey Nau, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
  
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 6, 2021

By: /s/ Jeffrey Nau  
Jeffrey Nau, Ph.D., M.M.S.  
President and Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER**

**PURSUANT TO**

**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Oyster Point Pharma, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel Lochner, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
  
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 6, 2021

By: /s/ Daniel Lochner  
Daniel Lochner  
Chief Financial Officer  
*(Principal Financial and Accounting Officer)*