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 June 30, 2020

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	**81-1030955**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
202 Carnegie Center, Suite 109 Princeton, New Jersey	**08540**
(Address of principal executive offices)	**(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	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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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 July 31, 2020, the registrant had 25,752,939 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 (DED) 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 DED 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 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, 2019 and the Company’s Quarterly Report on Form 10-Q for the three months ended March 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 you are cautioned not to unduly rely upon these statements.

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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)

	June 30, 2020	December 31, 2019
ASSETS		
Current Assets		
Cash and cash equivalents	$ 226,748	$ 139,147
Prepaid expenses and other current assets	1,816	3,033
Total current assets	228,564	142,180
Property and equipment, net	483	181
Restricted cash	61	51
Right-of-use assets, net	874	797
Total Assets	$ 229,982	$ 143,209
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 3,759	$ 507
Accrued expenses and other current liabilities	4,526	4,596
Lease liabilities	400	296
Total current liabilities	8,685	5,399
Lease liabilities, non-current	482	512
Total Liabilities	9,167	5,911
Commitments and Contingencies (Note 8)		
Stockholders' Equity		
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, 25,743,405 and 21,366,950 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	26	21
Additional paid-in capital	337,003	221,508
Accumulated deficit	(116,214)	(84,231)
Total Stockholders' Equity	220,815	137,298
Total Liabilities and Stockholders' Equity	$ 229,982	$ 143,209

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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 8,554	$ 8,101	$ 19,894	$ 10,506
General and administrative	6,940	3,132	12,529	4,737
Total operating expenses	15,494	11,233	32,423	15,243
Loss from operations	(15,494)	(11,233)	(32,423)	(15,243)
Other income, net	30	503	440	753
Net loss and comprehensive loss	$ (15,464)	$ (10,730)	$ (31,983)	$ (14,490)
Net loss per share, basic and diluted	$ (0.66)	$ (7.60)	$ (1.43)	$ (10.26)
Weighted average shares outstanding, basic and diluted	23,442,530	1,412,354	22,405,031	1,412,161

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

OYSTER POINT PHARMA, INC.
CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	—	$ —	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
Balance at March 31, 2020	—	$ —	21,370,480	$ 21	$ 222,692	$ (100,750)	$ 121,963
Net loss	—	—	—	—	—	(15,464)	(15,464)
Issuance of common stock upon follow-on equity offering, net of issuance costs of $8,125	—	—	4,312,500	5	112,620	—	112,625
Issuance of common stock upon exercise of stock options	—	—	60,425	—	82	—	82
Stock-based compensation expense	—	—	—	—	1,609	—	1,609
Balance at June 30, 2020	—	$ —	25,743,405	$ 26	$ 337,003	$ (116,214)	$ 220,815

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	7,611,691	$ 43,001	1,411,966	$ 1	$ 276	$ (38,520)	$ (38,243)
Net loss	—	—	—	—	—	(3,760)	(3,760)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $146	6,015,431	84,852	—	—	—	—	—
Stock-based compensation	—	—	—	—	40	—	40
Balance at March 31, 2019	13,627,122	$ 127,853	1,411,966	$ 1	$ 316	$ (42,280)	$ (41,963)
Net loss	—	—	—	—	—	(10,730)	(10,730)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $2	566,159	$ 8,000	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	7,060	—	7	—	7
Stock-based compensation	—	—	—	—	1,175	—	1,175
Balance at June 30, 2019	14,193,281	$ 135,853	1,419,026	$ 1	$ 1,498	$ (53,010)	$ (51,511)

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

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

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (31,983)	$ (14,490)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,789	1,215
Depreciation and amortization	40	—
Reduction in the carrying amount of the right-of-use assets	188	26
Changes in assets and liabilities:		
Prepaid expenses and other assets	1,217	(3,664)
Accounts payable	3,252	1,620
Change in lease liabilities	(207)	(26)
Accrued expenses and other current liabilities	(394)	801
Net cash used in operating activities	(25,098)	(14,518)
Cash flows from investing activities		
Purchase of property and equipment	(342)	(69)
Net cash used in investing activities	(342)	(69)
Cash flows from financing activities		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	92,852
Payment of deferred offering costs	—	(92)
Proceeds from follow-on equity offering, net of issuance costs	112,965	—
Proceeds from the issuance of common stock upon exercise of stock options	86	7
Net cash provided by financing activities	113,051	92,767
Net increase in cash, cash equivalents and restricted cash	87,611	78,180
Cash, cash equivalents and restricted cash at the beginning of the period	139,198	5,228
Cash, cash equivalents and restricted cash at the end of the period	$ 226,809	$ 83,408
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 226,748	$ 83,357
Restricted cash	61	51
Cash, cash equivalents and restricted cash	$ 226,809	$ 83,408
Supplemental cash flow information		
Right-of-use for office space and office equipment acquired through leases	$ 320	$ —
Supplemental non-cash flow information		
Unpaid additions to property and equipment, net	$ —	$ 8
Unpaid offering costs	$ 340	$ 196

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) was incorporated in the state of Delaware on June 30, 2015. From inception through June 30, 2020, the Company has been primarily engaged in business planning, research, clinical development of its lead therapeutic product candidates, recruiting and raising capital. 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.

Liquidity

The Company incurred net losses of $32.0 million and $14.5 million for the six months periods ended June 30, 2020 and 2019, respectively, and had an accumulated deficit of $116.2 million as of June 30, 2020. The Company has historically financed its operations primarily through the sale and issuance of its securities. The Company completed its initial public offering (IPO) in November of 2019, selling 5,750,000 shares of common stock at a price of $16.00 per share. The net proceeds from the offering were $82.1 million. On May 19, 2020, the Company completed its follow-on equity offering selling 4,312,500 shares of common stock at a price of $28.00 per share. The net proceeds from the offering were $112.6 million. To date, none of the Company's product candidates have been approved for sale and therefore it has not generated any revenue from product sales. The Company expects to incur increased sales and marketing expenses with the commercialization of new and existing products, if approved for sale, as well as increased research and development expenses as it develops additional product candidates. In addition, the Company expects its operating losses to continue to increase for the foreseeable future.

The Company is subject to risks and uncertainties as a result of the SARS-CoV-2 virus pandemic. The pandemic, which has continued to spread, 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 $226.7 million as of June 30, 2020. 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 June 30, 2020 and as of December 31, 2019, the results of operations for the three and six months ended June 30, 2020 and 2019, and cash flows for the six months ended June 30, 2020 and 2019. While management believes that the disclosures presented are adequate to make the information not misleading, these unaudited condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto in the Company's latest year-end financial statements, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019. 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. Organization and Summary of Significant Accounting Policies* in the Annual Report on Form 10-K for the year ended December 31, 2019. 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, 2019.

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.

Recently adopted accounting pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740) - Simplifying the Accounting for Income Taxes, which simplifies various aspects related to the accounting for income taxes. This ASU removes exceptions to the general principles in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. For public companies, this ASU is effective for interim and annual reporting periods beginning after December 15, 2020. Early adoption is permitted. The Company adopted ASU 2019-12 and its adoption did not have a material effect on the Company's financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements on fair value measurements. This ASU removes the requirement to disclose: the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; the policy for timing of transfers between levels; and the valuation processes for Level 3 fair value measurements. For public business entities, this ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2018-13 and its adoption did not have a material effect on the Company's financial statements and related disclosures.

Recently issued accounting pronouncements not yet adopted

In March 2020, the FASB issued ASU No. 2020-03, *Codification Improvements to Financial Instruments*. This ASU improves and clarifies various financial instruments topics, including the current expected credit losses standard issued in 2016. The ASU includes seven different issues that describe the areas of improvement and the related amendments to GAAP, intended to make the standards easier to understand and apply by eliminating inconsistencies and providing clarifications. The amendments have different effective dates. The Company is currently evaluating the impact the adoption of this ASU will have on its financial statements and related disclosures, but does not expect adoption will have a material impact on the Company's financial statements and 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 June 30, 2020, financial assets measured and recognized at fair value on a recurring basis were as follows (in thousands):

	Fair Value Measurements at June 30, 2020			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds	$ 225,748	$ —	$ —	$ 225,748
Total fair value of assets	$ 225,748	$ —	$ —	$ 225,748

As of December 31, 2019, financial assets measured and recognized at fair value on a recurring basis were as follows (in thousands):

	Fair Value Measurements at December 31, 2019			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds	$ 138,147	$ —	$ —	$ 138,147
Total fair value of assets	$ 138,147	$ —	$ —	$ 138,147

Money market funds are included in cash and cash equivalents on the 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 and 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.

There were no financial liabilities measured and recognized at fair value as of June 30, 2020 and December 31, 2019.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are money market funds included in cash and cash equivalents on the 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):

	June 30, 2020	December 31, 2019
Accrued compensation	1,481	1,214
Accrued professional services	1,199	1,163
Accrued research and development expense	1,846	2,219
Total accrued expenses and other current liabilities	$ 4,526	$ 4,596

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:

	June 30, 2020	December 31, 2019
Outstanding options under the 2016 Plan	2,678,641	2,748,434
Outstanding options under the 2019 Plan	603,245	29,466
Equity awards available for grant under the 2019 Plan	2,124,701	2,747,047
Unvested restricted stock units (RSUs)	77,530	23,125
Shares reserved for purchase under the ESPP [(a)]	270,000	270,000
Total	5,754,117	5,818,072

[(a)] — Employee Stock Purchase Plan approved in October 2019, as further described in *Note 5. Equity Incentive Plans*.

For further discussion on options and RSUs granted, exercised and cancelled during the six months ended June 30, 2020, see *Note 5. Equity Incentive Plans*.

Equity Offerings

On May 19, 2020, the Company completed its follow-on public offering selling 4,312,500 shares of common stock at a price to the public of $28.00 per share. The net proceeds from the offering were $112.6 million.

On November 4, 2019, upon the closing of the IPO, all outstanding shares of redeemable convertible preferred stock were converted into an aggregate of 14,193,281 shares of the Company’s common stock and $135.9 million of mezzanine equity was reclassified to common stock and additional paid-in capital. As of June 30, 2020 and December 31, 2019, there were no shares of redeemable convertible preferred stock issued and outstanding.

On February 15, 2019, the Company executed the Series B Preferred Stock Purchase Agreement to sell 6,581,590 shares of Series B redeemable convertible preferred stock. In February and April of 2019, the Company received gross cash proceeds of $85.0 million and $8.0 million, respectively, from the sale of Series B redeemable convertible preferred stock.

5. Equity Incentive Plans

In October 2019, the Company's Board of Directors (BOD) and stockholders approved the 2019 Equity Incentive Plan (the 2019 Plan). The 2019 Plan provides for the granting of stock options, restricted stock, restricted stock units, stock appreciation rights, performance units, and performance shares to the Company's employees, directors, and others.

The exercise price of an incentive stock option (ISO) and non-qualified stock option (NSO) shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the BOD. The exercise price of an ISO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, as determined by the BOD. To date, outstanding options have a term of 10 years and generally vest monthly over a four-year period.

In October 2019, the Company's BOD and stockholders also approved the 2019 Employee Stock Purchase Plan (the ESPP), which qualifies as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code, and pursuant to which 270,000 shares of common stock were reserved for future issuance. The ESPP is designed to enable eligible employees to purchase shares of the Company's common stock at a discount on a periodic basis through payroll deductions. There have been no ESPP purchases to date.

Stock Options

The following table summarizes stock option activity under the 2016 Plan and the 2019 Plan during the six months ended June 30, 2020 (in thousands, except share 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
Balance, January 1, 2020	2,777,900	$ 4.59	8.7	$ 55,146
Options granted	575,029	32.40		
Options exercised	(63,955)	1.34		1,874
Options canceled	(7,088)	17.52		91
Balance, June 30, 2020	3,281,886	9.50	8.5	65,634
Shares vested and exercisable as of June 30, 2020	1,289,392	2.29	7.9	34,283
Vested and expected to vest as of June 30, 2020	3,281,886	$ 9.50	8.5	$ 65,634

The weighted average grant date fair value of options granted during the six months ended June 30, 2020 was $23.75 per share. As of June 30, 2020, the total unrecognized stock-based compensation expense for stock options was $20.4 million, which is expected to be recognized over a weighted average period of 3.3 years.

Restricted Stock Units

Restricted stock units (RSUs) consist of restricted stock unit awards which are granted to the Company's employees and directors. 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 six months ended June 30, 2020 was as follows (in thousands, except share and per share data):

	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
Outstanding at January 1, 2020	23,125	$ 16.00	2.8	$ 565
Restricted stock units granted	54,405	28.03		1,525
Balance, June 30, 2020	77,530	24.44	1.4	2,239
Shares vested as of June 30, 2020	—	—		—
Vested and expected to vest as of June 30, 2020	77,530	$ 24.44	1.4	$ 2,239

As of June 30, 2020, the total unrecognized stock-based compensation expense for RSUs was $1.7 million, which is expected to be recognized over a weighted average period of 1.2 years.

Fair Value of Common Stock

Prior to the IPO, the fair value of the Company’s common stock underlying the stock options was determined by the Board of Directors with assistance from management and, in part, on input from an independent third-party valuation firm. The Board of Directors determined the fair value of common stock by considering a number of objective and subjective factors, including valuations of comparable companies, sales of convertible preferred stock, operating and financial performance, the lack of liquidity of the Company’s common stock and the general and industry-specific economic outlook. Subsequent to the IPO, the fair value of the Company’s common stock is determined based on its closing market price.

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 239	$ 209	$ 456	$ 214
General and administrative	1,370	966	2,333	1,001
Total stock-based compensation expense	$ 1,609	$ 1,175	$ 2,789	$ 1,215

6. 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):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Numerator:				
Net loss	$ (15,464)	$ (10,730)	$ (31,983)	$ (14,490)
Denominator:				
Weighted average shares outstanding, basic and diluted	23,442,530	1,412,354	22,405,031	1,412,161
Net loss per share, basic and diluted	$ (0.66)	$ (7.60)	$ (1.43)	$ (10.26)

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:

	As of June 30,	
	2020	**2019**
Series A redeemable convertible preferred stock	—	7,611,691
Series B redeemable convertible preferred stock	—	6,581,590
Options to purchase common stock	3,281,886	2,321,804
Unvested restricted stock units	77,530	—
Total	3,359,416	16,515,085

7. Leases

Lease Obligations

In April 2019, the Company entered into a non-cancelable operating lease for office space in Princeton, New Jersey, commencing on July 1, 2019, for a period of three years from the commencement date. In January 2020, the Company amended this lease to include additional office space, with the same terms as the original lease. Total future minimum lease payments under this amendment are $0.9 million as of June 30, 2020**.** The total lease payments required over the life of this lease are $1.2 million. The remaining lease term was 2.1 years as of June 30, 2020. Rent expense was $0.2 million and less than $0.1 million for the six months ended June 30, 2020 and 2019, respectively.

The Company leases certain office equipment under finance leases with remaining lease terms of 2.2 to 2.8 years. At the commencement date, the Company determined the amount of lease liability using a discount rate of 3%, which management determined represents the rate implicit in the lease. Interest expense and amortization expense for the finance leases was immaterial for the three and six months ended June 30, 2020 and 2019, respectively.

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

	June 30, 2020	December 31, 2019
Operating lease right-of-use asset	$ 832	$ 783
Finance lease right-of-use asset	42	14
Total right-of-use asset	$ 874	$ 797
Operating lease liabilities	$ 382	$ 290
Finance lease liabilities	18	6
Total lease liabilities	$ 400	$ 296
Operating lease liabilities, non-current	$ 454	$ 500
Finance lease liabilities, non-current	28	12
Total lease liabilities, non-current	$ 482	$ 512

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

As of June 30, 2020	Finance Leases	Operating Leases	Total
2020 (remainder)	$ 9	$ 214	$ 223
2021	18	432	450
2022	16	254	270
2023	4	—	4
Total undiscounted cash flows	47	900	947
Less: imputed interest	(1)	(64)	(65)
Total lease liability	46	836	882
Less: current portion	(18)	(382)	(400)
Lease liability	$ 28	$ 454	$ 482

8. Commitments and Contingencies

Asset Purchase of OC-02

In October 2016, the Company entered into an asset purchase agreement pursuant to which it acquired the compound OC-02. The agreement provides for milestone payments of up to $37.0 million upon achievement of certain milestone events. The agreement also provides for royalty payments in the mid-single digit percentage on covered product net worldwide

sales. The Company's obligation to pay royalties will terminate at the latter of patent expiration in each country or ten years. In addition, the Company is required to pay 15% of any (i) licensing revenue received that is related to OC-02 and (ii) revenue received from the sale of OC-02, up to a maximum aggregate amount of $10.0 million. No milestone was achieved or probable to be achieved or royalties payable accrued as of June 30, 2020 and as of December 31, 2019.

License Agreement

On October 18, 2019, the Company entered into a non-exclusive patent license agreement (the 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 product. Under the terms of the agreement, the Company made an upfront payment to Pfizer of $5 million. If the Company successfully commercializes OC-01, it may be required to pay a single milestone payment in the very low double-digit millions and tiered royalties on net sales of OC-01 at percentages ranging from the mid-single digits to the mid-teens. The royalty obligation to Pfizer will commence upon the first commercial sale of OC-01 and will 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 June 30, 2020 and as of December 31, 2019.

Contingencies and Indemnifications

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.

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications, including for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

The Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is not specified in the agreements; however, the Company has director and officer insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid.

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 operation. 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 and six months ended June 30, 2020 and 2019. Also refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2019, 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 significant 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 liquidity position, sources and uses of cash, capital resources and requirements, commitments, and off-balance sheet arrangements; and
- Critical accounting policies which are most important to both the portrayal of the Company's financial condition and results of operations, and which require management's most difficult, subjective or complex judgment.

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, 2019 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), 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 (DED). OC-01’s novel mechanism of action is designed to re-establish tear film homeostasis by activating the trigeminal parasympathetic pathway and stimulating the glands and cells responsible for natural tear film production. Based on OC-01’s clinical trial results and its rapid onset of action, the Company believes OC-01, if approved, has the potential to become the new standard of care and redefine how DED is treated for millions of patients. The Company believes that targeting the parasympathetic nervous system through the use of locally administered cholinergic agonists has the potential to treat a wide range of diseases and disorders. The Company has identified several indications, including several outside of ophthalmology, where this approach could provide a meaningful benefit to patients.

Since its formation in June 2015, the Company has devoted substantially all of its resources to developing its product candidates. The Company has incurred significant operating losses to date. The Company’s net losses were $32.0 million and $14.5 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, the Company had an accumulated deficit of $116.2 million. The Company expects that its operating expenses will increase significantly as it advances its 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 does not have any products approved for sale and has not generated any revenue since inception. The Company’s ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of its product candidates. Until such time as it can generate significant revenue from product sales, if ever, the Company expects to finance its operations through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate funding may not be available to the Company on acceptable terms, or at all. If the Company fails to raise capital or enter into such agreements as and when needed, it may have to significantly delay, scale back or discontinue the development and commercialization of its product candidates.

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 is approved, the Company intends to deploy a specialty sales force at the launch of OC-01 of approximately 150 to 200 field representatives.

Recent Events

ONSET-2 Phase 3 positive Top-line Results

The Company released the results of the ONSET-2 Phase 3 clinical trial during the second quarter of 2020. During the ONSET-2 Phase 3 clinical trial conducted in 758 subjects, OC-01 demonstrated a statistically significant improvement (as compared to placebo) in signs of DED in both the 0.6 mg/ml and 1.2 mg/ml dose groups and statistically significant improvements (as compared to placebo) in both signs and symptoms of DED in the 1.2 mg/ml dose group.

With the completion of the ONSET-2 Phase 3 clinical trial, as well as the long-term safety follow-up of the ONSET-1 Phase 2b clinical trial, both of which are considered to be pivotal clinical trials, the Company plans to submit a New Drug Application (NDA) for OC-01 for the treatment of signs and symptoms of DED to the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2020.

Follow-On Equity Offering

On May 19, 2020, the Company completed its follow-on public offering of 4,312,500 shares of its common stock at a price to the public of $28.00 per share. The net proceeds from the offering were $112.6 million.

Impact of the SARS-CoV-2 virus Pandemic

In March 2020, the World Health Organization declared the SARS-CoV-2 virus outbreak to be a pandemic. Also, in March of 2020, due to the SARS-CoV-2 virus pandemic, the Company experienced an impact at select clinical trial sites where ophthalmology practices were closed, or subjects were unable to attend visits, or where clinical trial sites did not feel comfortable putting their staff or subjects into a controlled adverse environment (CAE), which limited the Company's ability to assess the related secondary endpoint in its ONSET-2 study for those subjects. The Company then conducted a further post-hoc analyses on the data, which led to discovering additional treatment benefits in the 1.2 mg/ml dose group that were not captured with the statistical method used for analysis of the secondary endpoint. The Company intends to discuss with the FDA the appropriateness of its original secondary endpoint analysis and interpretation of the treatment benefit with the CAE of the 1.2 mg/ml dose group based on these post hoc analyses in the context of its planned NDA submission in the fourth quarter of 2020.

During the six months ended June 30, 2020, 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 outbreak affects 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 severity of the outbreak, 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 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 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.

The ultimate impact of the SARS-CoV-2 virus pandemic or a similar health epidemic is highly uncertain and subject to change. The Company has taken a variety of measures to ensure the availability and functioning of the Company's critical infrastructure and to promote the safety and security of its employees. These measures include requiring remote working arrangements for employees, which will continue through the end of 2020, investing in personal protective equipment, and providing sick leave to affected employees. In addition, Company management is currently evaluating and developing an

implementation plan for employees' safe return to the office once that option becomes feasible. The Company will continue to actively monitor the evolving situation related to the SARS-CoV-2 virus pandemic and may take further actions that alter its operations, including those that may be required by federal, state or local authorities, or that the Company determines are in the best interests of its employees, partners and other third-parties with whom the Company does business. At this point, the full extent to which the SARS-CoV-2 virus pandemic may affect the Company's business, operations, preclinical and clinical development and commercialization timelines and plans, including the resulting impact on its expenditures and capital needs, remains uncertain.

For further discussion of the risks that the Company faces as a result of the SARS-CoV-2 virus pandemic refer to Part II, Item 1A, Risk Factors, of this Quarterly Report on Form 10-Q.

Components of Operating Results

Revenue

The Company has not generated any revenue from product sales and does not expect to do so in the near future.

Operating Expenses

Research and Development Expenses

Substantially all of the Company's research and development expenses consist of expenses incurred in connection with the development of its product candidates. These expenses include fees paid to third parties to conduct certain research and development activities on the Company's behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for employees dedicated to the Company's research and product development and allocated overhead expenses, including rent, equipment, depreciation, information technology costs and utilities. The Company expenses both internal and external research and development expenses as they are incurred.

The Company does not allocate its costs by product candidate, as a significant amount of research and development expenses includes internal costs, such as payroll and other personnel expenses, laboratory supplies and allocated overhead expenses, and external costs, such as fees paid to third parties to conduct research and development activities on the Company's behalf, are not tracked by product candidate. Several of the Company's departments support multiple product candidate research and development programs, and therefore the costs cannot be allocated to a particular product candidate or development program. The Company tracks its research and development expenses by type of activity: clinical and preclinical, chemistry, manufacturing and controls (CMC), and other costs.

The Company is focusing substantially all of its resources on the development of its product candidates, particularly OC-01. The Company expects its research and development expenses to increase for at least the next few years, as it seeks to initiate additional clinical trials for its product candidates, complete its clinical programs, pursue regulatory approval of its product candidates and prepare for the possible commercialization of these product candidates. Predicting the timing or cost to complete the Company's clinical programs or validation of its commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of the Company's control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that it currently anticipates, the Company could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, the Company is unable to predict when or if its product candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, allocated overhead, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

The Company anticipates that its general and administrative expenses will increase as a result of increased personnel costs, expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the

applicable stock exchange and SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Other Income, Net

Other Income, net consists primarily of interest income earned on money market funds, which are included in cash and cash equivalents on the Company's condensed balance sheets.

Results of Operations

Comparison of the Results of Operations for the Three Months Ended June 30, 2020 and 2019

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

	Three Months Ended June 30,			
	2020	2019	$ Change	% Change
Operating expenses:				
Clinical, preclinical	$ 1,881	$ 2,206	$ (325)	(15) %
Chemistry, manufacturing and controls (CMC)	5,723	5,485	238	4 %
Other	950	410	540	132 %
Research and development	8,554	8,101	453	6 %
General and administrative	6,940	3,132	3,808	122 %
Loss from operations	(15,494)	(11,233)	(4,261)	38 %
Other income, net	30	503	(473)	(94) %
Net loss	$ (15,464)	$ (10,730)	$ (4,734)	44 %

Research and Development Expenses

Research and development expenses increased by $0.5 million during the three months ended June 30, 2020 compared to the three months ended June 30, 2019, primarily due to the Company's advancement of OC-01 development and higher employee headcount, which resulted in an increase in payroll and personnel-related expense, including salaries, bonuses, benefits and stock-based compensation, partially offset by lower expenses for clinical and preclinical studies.

General and Administrative Expenses

General and administrative expenses increased by $3.8 million during the three months ended June 30, 2020 compared to the three months ended June 30, 2019. The increase was due to higher headcount and reflects an increase in payroll and personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation of $1.8 million. Additionally, there was an increase in other general and administrative expenses of $1.6 million due to expansion of the Company's organization and operating as a publicly traded company. The Company also incurred higher commercial planning expenses of $0.4 million in anticipation of a U.S. launch of OC-01, if approved, in the fourth quarter of 2021.

Other Income, Net

Other income, net decreased by $0.5 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019, primarily due to lower rate of return on the money market funds earned during the period.

Comparison of the Six Months Ended June 30, 2020 and 2019

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

	Six Months Ended June 30,			
	2020	2019	$ Change	% Change
Operating expenses:				
Clinical, preclinical	$ 7,993	$ 3,482	$ 4,511	130 %
Chemistry, manufacturing and controls (CMC)	9,560	6,486	3,074	47 %
Other	2,341	538	1,803	335 %
Research and development	19,894	10,506	9,388	89 %
General and administrative	12,529	4,737	7,792	164 %
Loss from operations	(32,423)	(15,243)	(17,180)	113 %
Other income, net	440	753	(313)	(42)%
Net loss	$ (31,983)	$ (14,490)	$ (17,493)	121 %

Research and Development Expenses

Research and development expenses increased by $9.4 million during the six months ended June 30, 2020 compared to the six months ended June 30, 2019. The increase in clinical, preclinical, and CMC expense of $7.6 million was primarily due to an increase in expense related to CROs and CMOs in connection with the advancement of OC-01, as well as higher employee headcount, which resulted in an increase in payroll and personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation. The increase of $1.8 million in other research and development expense primarily relates to an increase in costs related to data management, quality and regulatory costs incurred in connection with higher employee headcount and the advancement of OC-01.

General and Administrative Expenses

General and administrative expenses increased by $7.8 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019. The increase was primarily driven by additional payroll and personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation of $3.8 million, higher general and administrative expenses of $3.4 million due to expansion of the Company's organization, as well as additional costs incurred by the Company due to operating as a publicly traded company.

Other Income, Net

Other income, net decreased by $0.3 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, 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 June 30, 2020 and December 31, 2019, the Company had cash and cash equivalents of $226.7 million and $139.1 million, respectively.

On May 19, 2020, the Company completed its follow-on public offering selling 4,312,500 shares of common stock at a price to the public of $28.00 per share. The net proceeds from the offering were $112.6 million.

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. As a result, the Company did not apply for, nor received, assistance under the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act).

To date, the Company has not generated any revenue. Since its formation in June 2015, the Company has devoted substantially all of its resources to developing its product candidates. It has incurred net losses of $32.0 million and $14.5 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, the Company had an accumulated deficit of $116.2 million. The Company expects that operating expenses will increase significantly as it advances its 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 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 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 expects to continue to incur significant losses for the foreseeable future, and expects the losses to increase as it continues the development of, and seeks regulatory approvals for, its product candidates and begins to commercialize any approved products. 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 continue to require additional capital to develop its product candidates and fund operations for the foreseeable future. It may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements 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 its 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 its product candidates;
- the scope and costs of development and commercial manufacturing and supply activities;
- the cost and timing associated with commercializing the 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;
- the Company's efforts to enhance operational systems and its ability to attract, hire and retain qualified personnel, including personnel to support the development of its product candidates and, ultimately, the sale of 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 and financial condition.

See the section of this Quarterly Report on Form 10-Q titled “Risk Factors”, as well as Item 1A. Risk Factors to the Annual Report on Form 10-K for the year ended December 31, 2019 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 and cash equivalents for each of the periods presented below (in thousands):

	Six Months Ended June 30,		
	2020	2019	$ Change
Net cash (used in) provided by:			
Operating activities	$ (25,098)	$ (14,518)	$ (10,580)
Investing activities	(342)	(69)	(273)
Financing activities	113,051	92,767	20,284
Net increase in cash and cash equivalents	$ 87,611	$ 78,180	$ 9,431

Cash Flows Used in Operating Activities

Net cash used in operating activities increased by $10.6 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, due to higher net loss adjusted for non-cash items during the period, partially offset by an increase in working capital of $5.1 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 to submit an NDA for the Company's lead product candidate, OC-01, to the FDA in the fourth quarter of 2020.

Cash Flows Used in Investing Activities

Net cash used in investing activities increased by $0.3 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, primarily related to partial payment for equipment to be used in manufacturing for OC-01.

Cash Flows Provided by Financing Activities

Net cash provided by financing activities increased by $20.3 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019. The increase was primarily due to the higher proceeds generated from the Company's follow-on offering on May 19, 2020, compared to the proceeds received for the issuance of redeemable preferred stock in the first half of 2019.

Contractual Obligations and Commitments

As of June 30, 2020, there have been no material changes from 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, 2019.

Off-Balance Sheet Arrangements

As of June 30, 2020, 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 Annual Report on Form 10-K for the year ended December 31, 2019.

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 elsewhere 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.

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 June 30, 2020, the Company had cash equivalents of $225.7 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 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

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in the Company's reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in the Company's reports filed or submitted under the Exchange Act is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

As of June 30, 2020, 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 ineffective as of June 30, 2020 due to the material weaknesses in the Company's control environment and formal accounting policies identified in the Annual Report on Form 10-K for the year ended December 31, 2019. The first previously identified material weakness is that the Company did not design or maintain an effective control environment commensurate with its financial reporting requirements and specifically, the Company lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. This material weakness contributed to an additional material weakness in that the Company did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliation and journal entries.

Notwithstanding the identified material weaknesses, management, including Chief Executive Officer and Chief Financial Officer, believes the financial statements included in this Quarterly Report on Form 10-Q fairly represent in all material respects the Company's financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. GAAP.

Remediation of the Material Weaknesses

The Company is committed to remediating the material weaknesses in its control environment and formal accounting policies. The Company initiated a remediation plan at the beginning of 2020 and has implemented the following actions as of August 5, 2020: (i) hired additional qualified accounting, finance and IT personnel to ensure proper analysis, recording and disclosure of accounting matters in a timely and accurate manner; and (ii) designed and implemented month-end processes and control procedures to assist in the accounting and financial reporting close cycles. The Company intends to implement additional measures as part of its remediation plan, including the implementation of additional formal accounting policies and procedures. While the Company has made progress in implementing the remediation initiatives outlined above, these actions alone were not sufficient to fully remediate the material weaknesses in internal control discussed above. Company management will continue to review the effectiveness of its internal control policies, procedures and controls and make changes or implement further actions as needed. After the remediation plan is fully implemented, the Company intends to perform testing to determine operating effectiveness of its internal controls over financial reporting.

Changes in Internal Control over Financial Reporting

Except as otherwise disclosed above, there have been no changes in the Company's internal control over financial reporting during the six months ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect the Company's internal control over financial reporting.

Limitations on the Effectiveness of Disclosure Controls and Procedures

The Company's management, including the Chief Executive Officer and Chief Financial Officer, does not expect that disclosure controls and procedures or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and implemented, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues within a company are detected. The inherent

limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

PART II — OTHER INFORMATION

ITEM 1 — Legal Proceedings.

The Company is not currently involved in any litigation or legal proceedings that, in management's opinion, are likely to have any material adverse effect on its business. While the Company knows of no imminent legal action in which it is likely to be involved, it may in the future become engaged in litigation or other legal proceedings. Regardless of the outcome, litigation can have an adverse impact on the Company due to defense fees, settlement costs, demands on management attention, and other concerns.

ITEM 1A — Risk Factors.

Information regarding risk factors appears in Part I, Item 1A, Risk Factors, in the Company's 2019 Form 10-K. Except as presented below, there have been no material changes in the Company's risk factors since those reported in its 2019 Form 10-K.

Risks Related to the Company's Business

The Company is highly dependent on the success of its lead product candidate OC-01 for the treatment of dry eye disease. If it is unable to successfully obtain the marketing approvals necessary to commercialize OC-01 or experiences significant delays in doing so, or if after obtaining marketing approvals, the Company fails to commercialize this product candidate, its business will be materially harmed.

The Company has devoted a significant portion of its financial resources and business efforts to the development of OC-01 for the treatment of DED. Although it is also developing OC-01 for other indications and a second product candidate OC-02, the Company does not anticipate receiving marketing approvals for any product candidates other than OC-01 in the next several years. The Company's ability to generate revenues from product sales will depend on its obtaining marketing approval for and commercializing OC-01, and it cannot accurately predict when or if OC-01 will receive marketing approval for DED or a secondary indication. Because the Company has focused its resources and efforts on developing OC-01 for DED, it has limited resources and may fail to commit adequate resources to, or delay the pursuit of opportunities for, other indications or other product candidates that may have greater commercial potential, and its resource allocation decisions may cause the Company to fail to capitalize on viable product candidates and profitable market opportunities. If the Company fails to successfully develop OC-01 for DED, it may not be able to identify, assess and develop OC-01 for other indications or OC-02 or a second lead product candidate or other product candidates on a timely basis, which could materially affect Company's business, financial condition, results of operations and growth prospects.

OC-01 uses a novel and unproven therapeutic approach and mechanism of action to treat DED and therefore its efficacy and safety are difficult to predict, and there is no guarantee that OC-01 or any other product candidates will be approved by the FDA.

The Company is developing OC-01 as a preservative-free, aqueous nasal spray that will stimulate the lacrimal functional unit (LFU) to produce natural tear film. To the Company's knowledge, OC-01 represents the first pharmacological treatment approach for DED that is aimed at stimulating the LFU. Other than with respect to data from studies and trials of OC-01 and OC-02, there is limited or no clinical evidence showing that natural tear film can be produced through the stimulation of the LFU. For instance, even though OC-01 has shown promising results in preclinical studies and clinical trials for the treatment of DED, the Company may not succeed in demonstrating safety and efficacy of OC-01 for other indications, including neurotrophic keratitis (NK), which is the disease being studied in OLYMPIA, the Company's upcoming Phase 2 clinical trial. Advancing OC-01 as a novel product creates significant challenges for the Company, including:

- obtaining marketing approval;
- educating medical personnel, including eye care practitioners (ECPs), and patients regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating the Company's product candidates, if approved, into treatment regimens; and
- establishing the sales and marketing capabilities upon obtaining any marketing approvals to gain market acceptance.

The Company cannot guarantee that OC-01 or any of its other future product candidates will be approved by the FDA. Product candidates in later-stage clinical trials often fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA and other comparable foreign regulatory authorities despite having successfully progressed through preclinical studies and other clinical trials. In some instances, there can be significant variability in safety and efficacy results between different

clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. For example, although OC-01 met the primary endpoint in ONSET-2 in both the 1.2 mg/ml and 0.6 mg/ml dose groups, OC-01 nasal spray did not meet the secondary endpoint for patient-reported symptoms of eye dryness in a Controlled Adverse Environment (CAE) and other secondary endpoints in either dose group. Following completion of ONSET-2, the Company conducted additional analyses on a post-hoc basis of the data from its ONSET-2 study to support its planned NDA submission. The Company may also conduct additional post-hoc analyses on the results of clinical trials in the future. Post-hoc analyses performed after unmasking trial results can result in the introduction of bias, may not be predictive of success in any future clinical trials and are given less weight by regulatory authorities than pre-specified analyses. Additionally, the Company cannot guarantee that the safety profile of OC-01 in healthy volunteers and patients with DED will be replicated in trials and studies for other indications, such as NK. Assessments of efficacy can vary widely for a particular participant, and from participant to participant and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, the Company's clinical trial outcomes. In addition, participants treated with OC-01 may also be treated with other investigational drugs, prescription drugs or even over-the-counter treatments following the treatment period of the Company's OC-01 studies, any of which can cause side effects or adverse events that are unrelated to the Company's product candidate, but which are observed during the long-term safety follow-up for OC-01. The occurrence of such side effects or adverse events could have a negative impact on OC-01's safety profile.

If the Company experiences delays or difficulties in the enrollment of subjects or conduct of follow up visits in clinical trials, its receipt of necessary regulatory approvals could be delayed or prevented.

The Company may not be able to initiate or continue clinical trials for its product candidates if it is unable to locate and enroll a sufficient number of subjects to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Any difficulties the Company experiences relating to completion of patient visits in clinical trials, including as impacted by the SARS-CoV-2 virus, could delay regulatory approval for its product candidates.

Patient enrollment may be affected if the Company's competitors have ongoing clinical trials for product candidates that are under development for the same indications as its product candidates, and subjects who would otherwise be eligible for clinical trials instead enroll in clinical trials of the Company's competitors' product candidates. Patient enrollment for any of the Company's future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- participant eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- ECPs' and participants' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications the Company is investigating;
- efforts to facilitate timely enrollment in clinical trials;
- participant referral practices of ECPs;
- the ability to monitor participants adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective trial subjects;
- continued enrollment of prospective subjects by clinical trial sites;
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion; and
- disruptions or difficulties, or other restrictions, in initiating, enrolling, conducting or completing trials due to the SARS-CoV-2 virus outbreak.

The Company's inability to enroll a sufficient number of subjects for its clinical trials would result in significant delays or may require it to abandon one or more clinical trials altogether. Enrollment delays in the Company's clinical trials may result in increased development costs for its product candidates and jeopardize its ability to obtain marketing approval for the sale of its product candidates. Furthermore, even if the Company is able to enroll a sufficient number of subjects for its clinical trials, the Company may have difficulty maintaining enrollment of such subjects in its clinical trials.

The Company may also face challenges in collecting data from follow up visits related to its enrolled clinical trials. For example, due to the SARS-CoV-2 virus outbreak, select clinical trial sites in the Company's ONSET-2 clinical trial were closed and subjects were unable to attend visits per the trial protocol, which reduced the amount of data the Company was able to collect

for subjects at these affected centers with respect to primary and secondary endpoints. The Company believes that this inability to collect data had an adverse impact on the statistical powering of certain of its secondary endpoints in ONSET-2, and may impact its future clinical trial results.

Internal computer systems, or those used by the Company's third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer other breakdowns, cyber-attacks or information security breaches that could compromise the confidentiality, integrity, and availability of such systems and data, expose the Company to liability, and affect its reputation.

The Company is increasingly dependent upon information technology systems, infrastructure, and data to operate its business, particularly during the SARS-CoV-2 virus pandemic. The Company also relies on third party vendors and their information technology systems. Despite the implementation of security measures, the Company's internal computer systems and those of its CROs and other contractors and consultants may be vulnerable to damage from computer viruses or unauthorized access, or breached due to operator error, malfeasance or other system disruptions. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber-threats may be generic, or they may be custom-crafted against the Company's information systems. Over the past few years, cyber-attacks have become more prevalent, intense, sophisticated and much harder to detect and defend against. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering and/or other means. The Company and its third party vendors may not be able to anticipate all types of security threats, and the Company may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources. As a result of the SARS-CoV-2 virus pandemic, the Company may face increased cybersecurity risks due to its reliance on internet technology and the number of its employees that are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Although to its knowledge the Company and its vendors have not experienced any such material system failure or security breach to date, if a breakdown, cyber-attack or other information security breach were to occur and cause interruptions in the Company's operations, it could result in a material disruption of its development programs and business operations, whether due to a loss of trade secrets or other proprietary information or other similar disruption and the Company could incur liability and reputational damage. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in the Company's regulatory approval efforts and significantly increase its costs to recover or reproduce the data. Likewise, the Company relies on its third-party research institution collaborators for research and development of its product candidates and other third parties for the manufacture of its product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on the Company's business.

Cyber-attacks, breaches, interruptions or other data security incidents could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, regulatory penalties, significant remediation costs, disrupt key business operations and divert attention of management and key information technology resources. In the United States, notice of breaches of protected health information as defined under the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA) must be made to affected individuals, the U.S. Secretary of the Department of Health and Human Services (HHS), and for extensive breaches, notice may need to be made to the media or U.S. state attorneys general. Such a notice could harm the Company's reputation and its ability to compete. The HHS has the discretion to impose penalties without attempting to resolve violations through informal means. In addition, U.S. state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. There can be no assurance that the Company, its collaborators, CROs, vendors, and any other business counterparties will be successful in efforts to detect, prevent, protect against or fully recover systems or data from all break-downs, service interruptions, attacks or breaches of systems. In addition, the Company does not maintain standalone cyber-security insurance and has limited insurance coverage in the event of any breach or disruption of its or its collaborators', CROs', or vendors' systems, including any unauthorized access or loss of any personal data that the Company may collect, store or otherwise process. The costs related to significant security breaches or disruptions could be material and exceed the limits of any insurance coverage the Company may have. To the extent that any disruption or security breach were to result in a loss of, or damage to, the Company's data or systems, or inappropriate disclosure of confidential or proprietary information, including data related to its personnel, the Company could incur liability and the further development and commercialization of its product candidates could be delayed and its business and operations could be adversely affected and/or could result in the loss or disclosure of critical or sensitive data, which could result in financial, legal, business or reputational harm to the Company.

The Company's business is subject to complex and evolving U.S. and foreign laws and regulations, information security policies and contractual obligations relating to privacy and data protection, including the use, processing, and cross-border transfer of personal information. These laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to its business practices, or monetary penalties, and otherwise may harm the Company's business.

The Company receives, generates and stores significant and increasing volumes of sensitive information and business-critical information, including employee and personal data (including protected health information), research and development information, commercial information, and business and financial information. The Company heavily relies on external security and infrastructure vendors to manage its information technology systems and data centers. The Company faces a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of it being unable to adequately monitor, audit and modify its controls over its critical information. This risk extends to the third-party vendors and subcontractors the Company uses to manage this sensitive data.

The Company is subject to governmental regulation and risks related to privacy, security, and data protection, and its actual or perceived failure to comply with such obligations could harm its business.

A wide variety of provincial, state, national, and international laws, and regulations apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data. These data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions. For example, the collection and use of personal data in the European Union are governed by the European Union General Data Protection Regulation (GDPR), which became fully effective on May 25, 2018. The GDPR imposes stringent data protection requirements, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when the Company contracts with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries and in the context of clinical trials, the Company currently relies on patient informed consent as the legal basis for such transfers. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. The GDPR provides for penalties for noncompliance of up to the greater of €20 million or four percent of worldwide annual revenues. The GDPR applies extraterritorially, and the Company may be subject to the GDPR because of its data processing activities that involve the personal data of individuals located in the European Union, such as in connection with any European Union clinical trials. GDPR regulations may impose additional responsibility and liability in relation to the personal data that the Company processes, and it may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay the Company's development activities, and adversely affect its business, financial condition, results of operations and growth prospects. In addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, the Company has to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. For example, California recently enacted legislation, the California Consumer Privacy Act (CCPA), that, among other things, require covered companies to provide new disclosures to California consumers, and afford such consumers new abilities to opt-out of certain sales of personal information, that became effective on January 1, 2020. The CCPA was amended several times throughout 2018 and 2019, and it is unclear whether further modifications will be made to this legislation or how it will be interpreted. In addition, the CCPA requires covered companies to provide new disclosures to individuals and consumers in California, and afford such individuals and consumers new data protection rights, including the ability to opt-out of certain sales of personal information. The GDPR, CCPA and many other laws and regulations relating to privacy and data protection are still being tested in courts, and they are subject to new and differing interpretations by courts and regulatory officials. Additionally, the interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for the Company and data it receives, uses and shares, potentially exposing it to additional expense, adverse publicity and liability. The Company is working to comply with

the GDPR, CCPA and other privacy and data protection laws and regulations that apply to it, and it anticipates needing to devote significant additional resources to complying with these laws and regulations.

It is possible that the GDPR, CCPA or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with the Company's current policies and practices and compliance with such laws and regulations could require it to change its business practices and compliance procedures in a manner adverse to its business. The Company cannot guarantee that it is in compliance with all such applicable data protection laws and regulations and it cannot be sure how these regulations will be interpreted, enforced or applied to the Company's operations. Furthermore, other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules, and regulations, which could increase the Company's compliance costs and the risks associated with noncompliance. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with the Company's practices and its efforts to comply with the evolving data protection rules may be unsuccessful. The Company cannot guarantee that it or its vendors may be in compliance with all applicable international laws and regulations as they are enforced now or as they evolve. For example, the Company's privacy policies may be insufficient to protect any personal information it collects or may not comply with applicable laws. The Company's non-compliance could result in government-imposed fines or orders requiring that it change its practices, which could adversely affect its business. In addition to the risks associated with enforcement activities and potential contractual liabilities, the Company's ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to its policies, procedures and systems. In addition, if the Company is unable to properly protect the privacy and security of protected health information, it could be found to have breached its contracts.

The Company's actual or perceived failure to adequately comply with applicable laws and regulations relating to privacy and data protection, or to protect personal data and other data it processes or maintains, could result in regulatory enforcement actions against the Company, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, other lawsuits or reputational and damage, all of which could materially affect the Company's business, financial condition, results of operations and growth prospects.

Risks Related to Development and Commercialization of the Company's Product Candidates

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If clinical trials of the Company's product candidates, particularly OC-01, are prolonged or delayed, the Company may be unable to obtain required regulatory approvals, and therefore be unable to commercialize its product candidates on a timely basis or at all.

Before obtaining marketing approval from regulatory authorities for the sale of its product candidates, the Company must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. To date, the Company has focused substantially all of its efforts and financial resources on identifying, acquiring, and developing its product candidates, including conducting preclinical studies and clinical trials. Clinical testing is expensive and can take many years to complete, and the Company cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. The Company's inability to successfully complete preclinical and clinical development could result in additional costs to it and negatively impact its ability to generate revenue. The Company's future success is dependent on its ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates. The Company currently does not generate any revenues from sales of any products, and it may never be able to develop or commercialize a marketable product.

Each of the Company's product candidates will require additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, achieving and maintaining commercial-scale supply, building of a commercial organization, substantial investment and significant marketing efforts before the Company generates any revenues from product sales. The Company is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA or comparable foreign regulatory authorities, and it may never receive such regulatory approval for any of its product candidates. The Company may experience delays in its ongoing clinical trials and it does not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all.

The Company may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent its ability to receive marketing approval or commercialize OC-01, OC-02 or any other product candidates that it may develop, including:

- the Company may experience delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites
- the Company may fail to obtain sufficient enrollment in its clinical trials or participants may fail to complete its clinical trials;
- clinical trials of its product candidates may produce negative or inconclusive results, and it may decide, or regulators may require the Company, to conduct additional clinical trials or abandon product development programs;
- the Company may decide, or regulators or institutional review boards may require it, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require the Company to perform additional or unanticipated clinical trials to obtain approval or it may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving its product candidates, or such requirements may not be as it anticipates;
- the cost of clinical trials of its product candidates may be greater than it anticipates, and the Company may need to delay or suspend one or more trials until it completes additional financing transactions or otherwise receive adequate funding;
- the supply or quality of its product candidates or other materials necessary to conduct clinical trials of its product candidates may be insufficient or inadequate or may be delayed;
- the Company's product candidates may have undesirable side effects or other unexpected characteristics, causing it or its investigators, regulators or institutional review boards to suspend or terminate trials;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- the Company may experience delays due to the SARS-CoV-2 virus pandemic, including with respect to the receipt of product candidates or other materials, submission of NDAs, filing of INDs and starting any clinical trials for other indications or programs; and
- the Company may experience manufacturing delays due to the SARS-CoV-2 virus pandemic in its supply chain caused by a shortage of raw materials, a lack of employees on site at its suppliers due to illness, or a lack of productivity at its suppliers due to local or national government quarantine restrictions on coming to the workplace.

For example, due to the SARS-CoV-2 virus pandemic, the Company experienced an impact at select clinical trial sites during the month of March 2020 where ophthalmology practices were closed or subjects were unable to attend visits or where clinical trial sites did not feel comfortable putting their staff or subjects into a CAE, which limited the Company's ability to assess the related secondary endpoint in its ONSET-2 study for those subjects. The Company does not know whether any of its preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If the Company experiences delays in the completion of, or termination of, any clinical trial of its product candidates, or is unable to achieve clinical endpoints due to unforeseen events, such as the SARS-CoV-2 virus pandemic, the commercial prospects of its product candidates will be harmed, and its ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing its clinical trials will increase the Company's costs, slow down its product candidate development and approval process and jeopardize its ability to commence product sales and generate revenues. Significant clinical trial delays could also allow the Company's competitors to bring products to market before it does or shorten any periods during which the Company has the exclusive right to commercialize its product candidates and impair its ability to commercialize its product candidates and may harm its business and results of operations.

The commercial success of the Company's products depends on the availability and sufficiency of third party payor coverage and reimbursement.

Patients in the United States and elsewhere generally rely on third party payors to reimburse part or all of the costs associated with their prescription drugs. Accordingly, market acceptance of the Company's products is dependent on the extent to which third party coverage and reimbursement is available from third-party payors, including government health administration authorities (including in connection with government healthcare programs, such as Medicare and Medicaid), private healthcare insurers and other healthcare funding organizations.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which the Company may obtain regulatory approval. Coverage decisions may not favor new products when more established or lower cost therapeutic alternatives are already available. Even if the Company obtains coverage for a given product, the associated reimbursement rate may not be adequate to cover its costs, including research, development, intellectual property, manufacture, sale and distribution expenses, or may require copayments that patients find unacceptably high. Patients are unlikely to use the Company's products unless reimbursement is adequate to cover all or a significant portion of the cost of its products.

Coverage and reimbursement policies for products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for products among third party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly which will require the Company to provide scientific and clinical support for the use of its products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained.

In addition, the Company expects that the increased emphasis on managed care and cost containment measures in the United States by third party payors and government authorities to continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which the Company receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If the Company is unable to obtain and maintain sufficient third party coverage and adequate reimbursement for its products, the commercial success of these products may be greatly hindered and the Company's financial condition and results of operations may be materially and adversely affected.

The Company's business, operations and clinical development timelines and plans could be adversely affected by the effects of health epidemics, including the SARS-CoV-2 virus pandemic.

The Company's business, operations and clinical development timelines and plans could be adversely affected by health epidemics in regions where it has concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of CROs upon whom it relies. In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19, was reported to have surfaced in Wuhan. Since then, the SARS-CoV-2 virus has spread to multiple countries worldwide, including the United States, where the Company has planned and has ongoing preclinical studies and clinical trials. On March 11, 2020, the World Health Organization declared the outbreak of the SARS-CoV-2 virus to be a global pandemic. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended and demand for certain goods and services has fallen.

The President of the United States has declared the SARS-CoV-2 virus pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response and powers under the Defense Production Act, the legislation that facilitates the production of goods and services necessary for national security and for other purposes. In addition, in response to the SARS-CoV-2 virus pandemic, many state, local and foreign governments have put in place, and others in the future may put in place, quarantines, executive orders, shelter-in-place orders and similar government orders and restrictions in order to control the spread of the disease. Such orders or restrictions, and the perception that such orders or restrictions could occur, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects that could negatively impact productivity and disrupt the Company's business and operations. For example, the Company's headquarters and certain of its trial sites are located in New Jersey, and in March 2020, the Governor of New Jersey announced that all businesses, excluding essential services, must decrease their in-office workforce by 100%. While some of these governmental restrictions have begun to be lifted, the timing and extent to which such orders and restrictions will be removed remains uncertain. The Company has implemented a work-from-home policy for all employees, and it continues evaluating the situation as more information about the virus becomes available. Moreover, the Company's clinical development timelines and plans could be affected by the SARS-CoV-2 virus pandemic. Site initiation and patient enrollment could be delayed or suspended due to prioritization of hospital resources toward the SARS-CoV-2 virus pandemic. In addition, some patients may not be able to comply with clinical trial protocols and the ability to conduct follow up visits with treated patients may be limited if quarantines impede patient movement or interrupt healthcare services. For example, due to the SARS-CoV-2 virus pandemic, select clinical trial sites in ONSET-2 clinical trial were closed and subjects were unable to attend visits per the trial protocol, which reduced the number of patients for which the Company collected data on with respect to its primary and secondary endpoints. In addition, due to the SARS-CoV-2 virus pandemic, a number of clinical trial sites for ONSET-2 did not feel comfortable putting their staff or subjects into a controlled adverse environment (CAE), which limited the Company's ability to assess the related secondary endpoint for those subjects, which might have contributed to not achieving certain secondary endpoints in ONSET-2. The Company cannot assure that the inability to collect such data would not have an adverse impact on its future clinical trial results. Similarly, the Company's ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to SARS-CoV-2 virus pandemic could be adversely impacted.

If the SARS-CoV-2 virus pandemic continues to spread in the United States and elsewhere, the Company may experience disruptions, including those described above, that could severely impact its business, preclinical studies, and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate planned clinical trials;
- delays or difficulties in enrolling and retaining patients in clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the SARS-CoV-2 virus pandemic which may require the Company to change ways in which clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in the Company's clinical trials will acquire SARS-CoV-2 virus while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA to accept data from clinical trials in affected geographies;
- interruption or delays to the Company's sourced discovery and clinical activities;
- increased cybersecurity risks due to the Company's reliance on internet technology and the number of its employees that are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities; and
- disruption or constraints at manufacturers, which could result in product manufacturing delays.

Further, the spread of SARS-CoV-2 virus, which has caused a broad impact globally, may materially affect the Company economically. While the potential economic impact brought by and the duration of SARS-CoV-2 virus pandemic may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing the Company's ability to access capital, which could in the future negatively affect its liquidity. In addition, a recession or market correction resulting from the spread of SARS-CoV-2 virus pandemic could materially affect its business and value of Company's common stock.

The global SARS-CoV-2 virus pandemic continues to rapidly evolve, and the Company will continue to monitor the SARS-CoV-2 virus pandemic situation closely. The ultimate impact of the SARS-CoV-2 virus pandemic or a similar health epidemic is highly uncertain and subject to change. The Company does not yet know the full extent of the potential impacts on its business, clinical trials, healthcare systems or the global economy as a whole.

Risks Related to Government Regulation

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If the Company is ultimately unable to obtain regulatory approval for its product candidates, it will be unable to generate product revenue and its business will be substantially harmed.

The time required to obtain approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that the Company’s data is insufficient for approval and require additional preclinical, clinical or other data. Even if

the Company eventually completes clinical testing and receives approval of any regulatory filing for its product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve its product candidates for a more limited indication or a narrower patient population than it originally requested. For example, the fact that OC-01 did not achieve certain secondary endpoints in ONSET-2 could have an adverse effect on the Company's ability to obtain its desired label for OC-01, if approved. The Company has not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of its existing product candidates or any product candidates it may seek to develop in the future will ever obtain regulatory approval.

Further, development of the Company's product candidates and/or regulatory approval may be delayed for reasons beyond its control. For example, a U.S. federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018 and 2019, or diversion of resources to currently handle the SARS-CoV-2 virus pandemic public health emergency and pandemic may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting the Company's ability to progress development of its product candidates or obtain regulatory approval for its product candidates. In addition, the impact of SARS-CoV-2 virus pandemic may cause the FDA to allocate additional resources to product candidates focused on treating related illnesses, which could lead to longer approval processes for the Company's product candidates. Moreover, some of the Company's analyses of the ONSET-2 clinical trial data are post-hoc analyses and, although it believes that these post-hoc analyses can provide additional information regarding results from this clinical trial, retrospective analyses can result in the introduction of bias and may be given less weight by the FDA, including for purposes of determining whether to accept the Company's NDA for filing or approving its NDA. Finally, the Company's competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that its product candidates, or the clinical trials that support their approval, contain deficiencies. Such actions by its competitors could delay or even prevent the FDA from approving any of the Company's NDAs.

Applications for the Company's product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, FMA or other comparable foreign regulatory authorities may disagree with the design, implementation, or results of the Company's clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that the Company's product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude the Company's obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which the Company seeks approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the Company's interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of the Company's product candidates may not be sufficient to support the submission of an NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the Company may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which the Company contracts for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering the Company's clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in the Company failing to obtain regulatory approval to market any of its product candidates, which could materially affect its business, financial condition, results of operations 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's not able 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. There remain judicial, Congressional and executive branch challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed 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 has considered legislation that would 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 includes 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 eliminates the health insurer tax. The Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In December 2018, the Centers for Medicare & Medicaid Services (CMS) published a final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of $12 billion in “risk corridor” funding.

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. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, although it is unclear when the Supreme Court will make a decision. It is also unclear how such litigation and other efforts to repeal and replace the ACA 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. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the SARS-CoV-2 virus pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. 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’s budget proposal for the fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. In addition, the Trump administration previously released a “Blueprint” to lower drug prices and reduce out-of-pocket costs of prescription drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. The Department of Health and Human Services (HHS) has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1,

2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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 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, 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.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of the Company's business may rely, which could negatively impact its business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission (SEC) and other government agencies on which the Company's operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect the Company's business. For example, in recent years, including in 2013, 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities.

Separately, in response to the global pandemic of SARS-CoV-2 virus pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the SARS-CoV-2 virus pandemic. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process the Company's regulatory submissions, which could have a material adverse

effect on its business. Further, in the Company's operations as a public company, future government shutdowns could impact its ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

Changes in U.S. tax law may materially adversely affect the Company's financial condition, results of operations and cash flows.

On March 27, 2020, the CARES Act was signed into law to address the SARS-CoV-2 virus pandemic crisis. The CARES Act is an approximately $2 trillion emergency economic stimulus package that includes numerous U.S. federal income tax provisions, including the modification of: (i) net operating loss rules, (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163(j) of the Internal Revenue Code of 1986, as amended (the Code).

The Tax Act also significantly changed the U.S. federal income taxation of U.S. corporations. The Tax Act remains unclear in many respects and has been, and may continue to be, the subject of amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service (the IRS), which have lessened or increased certain adverse impacts of the Tax Act and may continue to do so in the future. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. The Company continues to work with its tax advisors to determine the full impact the Tax Act and the CARES Act will have. The Company's investors should consult with their legal and tax advisors with respect to both the Tax Act and the CARES Act and the potential tax consequences of investing in the Company's common stock.

The Company’s ability to use its net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.

The Company’s net operating loss carryforwards (NOLs) and certain other tax attributes could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. The Company’s NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. As of December 31, 2019, the Company had U.S. federal NOL carryforward balance of $61.1 million, $4.5 million of which will expire beginning in the year 2035, if unutilized, and $56.6 million which will carry forward indefinitely. As of December 31, 2019, the Company had state NOL carryforward balance of $61.8 million, which will expire beginning in the year 2035, if unutilized.

Under the Tax Act, federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely. Under the CARES Act, NOLs arising in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss. Due to the Company’s cumulative losses through December 31, 2019, it does not anticipate that such provision of the CARES Act will be relevant to it. The deductibility of federal NOLs, particularly for tax years beginning after December 31, 2020, may be limited. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

In addition, the Company’s NOLs and tax credit carryforwards are subject to review and possible adjustment by the IRS and state tax authorities. Under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change” (generally defined as a cumulative change in the Company’s ownership by “5-percent stockholders” that exceeds 50 percentage points over a rolling three-year period), the corporation’s ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. The Company determined in 2019 that no significant limitation would be placed on the utilization of its net operating loss and tax credit carryforwards due to prior ownership changes. The Company may, however, experience ownership changes in the future as a result of equity offerings or subsequent shifts in its stock ownership, some of which are outside its control. If the Company’s ability to utilize those NOLs and tax credit carryforwards becomes limited by an “ownership change” as described above, it may not be able to utilize a material portion of its NOLs and certain other tax attributes, which could have a material adverse effect on its cash flows and results of operations.

Risks Related to Reliance on Third Parties

The Company’s business operations and current and future relationships with healthcare professionals, clinical investigators, consultants, patient organizations, customers, CROs and third party payors in connection with its current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose the Company to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which the Company obtains marketing approval. The Company's current and future arrangements with healthcare professionals, including ECPs, clinical investigators, CROs, third-party payors and customers may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which the Company researches, markets, sells and distributes its products for which it obtains marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians, as defined by such law, and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. Additionally, beginning in 2022 for payments made, or ownership or investment interests held, in 2021, manufacturers' reporting requirements will extend to physician assistants, nurse practitioners, and other mid-level practitioners. The information reported is publicly available on a searchable website, with disclosure required annually; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products. In addition, certain state and local laws require the registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation (GDPR), which extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may increase the Company's responsibility and liability in relation to personal data that it processes and it may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if the Company's efforts to comply with GDPR or other applicable EU laws and regulations are not successful, it could adversely affect the Company's business in the European Union.

Efforts to ensure that the Company's current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that the Company's business practices, including the provision of stock options as compensation for consulting services to physicians and other healthcare providers, some of whom may be in a position to recommend, purchase and/or prescribe the

Company's product candidates, if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If the Company's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, the Company may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of its operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if the Company is successful in defending against any such actions that may be brought against it, the Company's business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom the Company expects to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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	Amended and Restated Certificate of Incorporation	8-K	001-39112	3.1	November 5, 2019
3.2	Amended and Restated Bylaws	8-K	001-39112	3.2	November 5, 2019
31.1*	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.				
31.2*	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.				
32.1*+	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.				
32.2*+	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.				
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				

* 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: August 5, 2020

By: /s/ Jeffrey Nau

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

President, Chief Executive Officer and Director

Date: August 5, 2020

By: /s/ Daniel Lochner

Daniel Lochner

Chief Financial Officer

Exhibit 31.1

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)) 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) 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

   (c) 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: August 5, 2020

By: /s/ Jeffrey Nau

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

Exhibit 31.2

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)) 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) 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

   (c) 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: August 5, 2020

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

Exhibit 32.1

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 June 30, 2020 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 result of operations of the Company.

Date: August 5, 2020

By: /s/ Jeffrey Nau

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

Exhibit 32.2

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 June 30, 2020 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 result of operations of the Company.

Date: August 5, 2020

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