
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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 September 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: 001-34475

OMEROS CORPORATION

(Exact name of registrant as specified in its charter)

Washington
(State or other jurisdiction of
incorporation or organization)

201 Elliott Avenue West
Seattle, Washington
(Address of principal executive offices)

91-1663741
(I.R.S. Employer
Identification Number)

98119
(Zip Code)

(206) 676-5000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

(Title of each class)	(Trading symbol)	(Name of each exchange on which registered)
Common Stock, \$0.01 par value per share	OMER	The Nasdaq Stock Market LLC

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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 5, 2020, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 61,652,326.

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 (the Securities Act) and Section 21E of the Securities Exchange Act of 1934 (the Exchange Act) which are subject to the “safe harbor” created by those sections for such statements. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical fact are “forward-looking statements.” Terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “likely,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” and similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

- our expectations related to obtaining separate payment status for OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% from the Centers for Medicare & Medicaid Services (CMS), the impact of a long-term or permanent absence of separate payment status for OMIDRIA on our business and financial condition, and our expectations regarding reimbursement coverage for OMIDRIA by commercial and government payers;
 - our estimates regarding how long our existing cash, cash equivalents, short-term investments and revenues will be sufficient to fund our anticipated operating expenses, capital expenditures and debt service obligations;
 - our expectations relating to demand for OMIDRIA from wholesalers, ambulatory surgery centers (ASCs) and hospitals, and our expectations regarding OMIDRIA product sales;
 - our plans and expectations for an alternative commercial strategy for OMIDRIA;
 - the severity and duration of the impact of the COVID-19 pandemic on our business, operations, clinical programs and financial results;
 - our plans for the marketing and distribution of OMIDRIA and our estimates of OMIDRIA chargebacks and rebates, distribution fees and product returns;
 - our expectations regarding the clinical, therapeutic and competitive benefits and importance of OMIDRIA and our product candidates;
 - our ability to design, initiate and successfully complete clinical trials and other studies for our products and product candidates and our plans and expectations regarding our ongoing or planned clinical trials, including for our lead MASP-2 inhibitor, narsoplimab (also referred to as OMS721), and for our other investigational candidates, including OMS527 and OMS906;
 - our plans and expectations regarding development of narsoplimab for the treatment of COVID-19 or COVID-19-associated acute respiratory distress syndrome (ARDS), including statements regarding the therapeutic potential of narsoplimab for treatment of COVID-19 and/or ARDS, discussions with government agencies regarding narsoplimab for treatment of COVID-19 or ARDS, plans for future manufacturing of narsoplimab, expectations for the treatment of additional COVID-19 patients in clinical trials or other settings and our expectations for receiving any regulatory approval or authorization from FDA or other regulatory body for narsoplimab in the treatment of COVID-19 patients;
 - with respect to our narsoplimab clinical programs, our expectations regarding: whether enrollment in any or all ongoing and planned clinical trials will proceed as expected; whether we can capitalize on the financial and regulatory incentives provided by orphan drug designations granted by the U.S. Food and Drug Administration (FDA), the European Commission (EC), or the European Medicines Agency (EMA); and whether we can capitalize on the regulatory incentives provided by fast-track or breakthrough therapy designations granted by the FDA;
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[Table of Contents](#)

- our expectations regarding clinical plans and anticipated or potential paths to regulatory approval of narsoplimab by the FDA and EMA in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), Immunoglobulin A (IgA) nephropathy, and atypical hemolytic uremic syndrome (aHUS);
- whether and when we will complete the rolling Biologics License Application (BLA) for narsoplimab in HSCT-TMA and whether and when FDA will accept our submission and grant accelerated or regular approval;
- whether and when a BLA may be filed with the FDA for narsoplimab in any other indication and whether FDA will grant accelerated or regular approval;
- whether and when a marketing authorization application (MAA) may be filed with the EMA for narsoplimab in any indication, and whether the EMA will grant approval for narsoplimab in any indication;
- our plans for the commercial launch of narsoplimab following any regulatory approval and our estimates and expectations regarding coverage and reimbursement for any approved products;
- our expectation that we will rely on contract manufacturers to manufacture OMIDRIA for commercial sale and to manufacture our product candidates for purposes of clinical supply and in anticipation of potential commercialization;
- our ability to raise additional capital through the capital markets or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;
- our expectations about the commercial competition that OMIDRIA and our product candidates, if commercialized, face or may face;
- the expected course and costs of existing claims, legal proceedings and administrative actions, our involvement in potential claims, legal proceedings and administrative actions, and the merits, potential outcomes and effects of both existing and potential claims, legal proceedings and administrative actions, as well as regulatory determinations, on our business, prospects, financial condition and results of operations;
- the extent of protection that our patents provide and that our pending patent applications will provide, if patents are issued from such applications, for our technologies, programs, products and product candidates;
- the factors on which we base our estimates for accounting purposes and our expectations regarding the effect of changes in accounting guidance or standards on our operating results; and
- our expected financial position, performance, revenues, growth, costs and expenses, magnitude of net losses and the availability of resources.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in this Quarterly Report on Form 10-Q under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in our other filings with the U.S. Securities and Exchange Commission (SEC). Given these risks, uncertainties and other factors, actual results or anticipated developments may not be realized or, even if substantially realized, may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements, which represent our estimates and assumptions only as of the date of the filing of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable law, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

OMEROS CORPORATION
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2020

INDEX

	<u>Page</u>
<u>Part I — Financial Information</u>	5
<u>Item 1.</u> <u>Financial Statements (unaudited)</u>	5
<u>Condensed Consolidated Balance Sheets</u>	5
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss</u>	6
<u>Condensed Consolidated Statements of Cash Flows</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2.</u> <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	22
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	35
<u>Item 4.</u> <u>Controls and Procedures</u>	35
<u>Part II — Other Information</u>	36
<u>Item 1.</u> <u>Legal Proceedings</u>	36
<u>Item 1A.</u> <u>Risk Factors</u>	36
<u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	40
<u>Item 6.</u> <u>Exhibits</u>	40
<u>Signatures</u>	41

PART I — FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****OMEROS CORPORATION****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except share and per share data)****(unaudited)**

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,075	\$ 3,084
Short-term investments	132,448	57,704
Receivables, net	37,379	35,185
Inventory	1,542	1,147
Prepaid expense and other assets	3,541	6,625
Total current assets	195,985	103,745
Property and equipment, net	2,950	3,829
Right of use assets	26,116	27,082
Restricted investments	1,154	1,154
Advanced payments, non-current	870	1,159
Total assets	<u>\$ 227,075</u>	<u>\$ 136,969</u>
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	\$ 7,017	\$ 5,328
Accrued expenses	36,948	46,627
Current portion of lease liabilities	3,754	3,504
Total current liabilities	47,719	55,459
Lease liabilities, non-current	29,717	32,318
Unsecured convertible senior notes, net	232,808	158,213
Deferred tax liability	4,157	—
Commitments and contingencies (Note 8)		
Shareholders' deficit:		
Preferred stock, par value \$0.01 per share, 20,000,000 shares authorized; none issued and outstanding at September 30, 2020 and December 31, 2019.	—	—
Common stock, par value \$0.01 per share, 150,000,000 shares authorized at September 30, 2020 and December 31, 2019; 61,651,152 and 54,200,810 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively.	616	542
Additional paid-in capital	747,457	625,048
Accumulated deficit	(835,399)	(734,611)
Total shareholders' deficit	(87,326)	(109,021)
Total liabilities and shareholders' deficit	<u>\$ 227,075</u>	<u>\$ 136,969</u>

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Product sales, net	\$ 26,114	\$ 29,856	\$ 63,181	\$ 78,389
Costs and expenses:				
Cost of product sales	401	278	815	464
Research and development	31,316	23,746	84,359	69,108
Selling, general and administrative	19,825	16,933	54,792	48,493
Total costs and expenses	51,542	40,957	139,966	118,065
Loss from operations	(25,428)	(11,101)	(76,785)	(39,676)
Loss on early extinguishment of debt	(13,374)	—	(13,374)	—
Interest expense	(6,882)	(5,715)	(18,763)	(16,846)
Other (expense) income	(633)	353	280	1,261
Loss before income taxes	(46,317)	(16,463)	(108,642)	(55,261)
Income tax benefit	7,854	—	7,854	—
Net loss	<u>\$ (38,463)</u>	<u>\$ (16,463)</u>	<u>\$ (100,788)</u>	<u>\$ (55,261)</u>
Comprehensive loss	<u>\$ (38,463)</u>	<u>\$ (16,463)</u>	<u>\$ (100,788)</u>	<u>\$ (55,261)</u>
Basic and diluted net loss per share	<u>\$ (0.66)</u>	<u>\$ (0.33)</u>	<u>\$ (1.81)</u>	<u>\$ (1.12)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>58,233,988</u>	<u>49,373,156</u>	<u>55,682,379</u>	<u>49,157,055</u>

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2020	2019
Operating activities:		
Net loss	\$ (100,788)	\$ (55,261)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	11,122	10,468
Non-cash interest expense	8,169	6,790
Depreciation and amortization	1,218	1,262
Loss on early extinguishment of debt	13,374	—
Deferred income tax	(7,854)	—
Fair value settlement upon termination of cap call contract	838	—
Changes in operating assets and liabilities:		
Receivables	(2,194)	(7,113)
Inventory	(395)	(1,085)
Prepaid expenses and other assets	3,533	959
Accounts payable and accrued expenses	(8,702)	6,921
Net cash used in operating activities	<u>(81,679)</u>	<u>(37,059)</u>
Investing activities:		
Purchases of property and equipment	(283)	(318)
Purchases of investments	(133,190)	(594)
Proceeds from the sale and maturities of investments	58,446	36,750
Net cash (used in) provided by investing activities	<u>(75,027)</u>	<u>35,838</u>
Financing activities:		
Proceeds from issuance of convertible senior notes, net of issuance costs	218,245	—
Purchases of capped calls related to convertible senior notes	(23,223)	—
Payments for repurchases of convertible senior notes	(125,638)	—
Proceeds from termination of capped call contracts	7,549	—
Proceeds from issuance of common stock, net	93,675	—
Proceeds upon exercise of stock options	4,978	5,034
Principal payments on finance lease liabilities	(889)	(813)
Net cash provided by financing activities	<u>174,697</u>	<u>4,221</u>
Net increase in cash and cash equivalents	17,991	3,000
Cash and cash equivalents at beginning of period	3,084	5,861
Cash and cash equivalents at end of period	<u>\$ 21,075</u>	<u>\$ 8,861</u>
Supplemental cash flow information		
Cash paid for interest	<u>\$ 8,564</u>	<u>\$ 6,811</u>
Property acquired under finance lease	<u>\$ 216</u>	<u>\$ 886</u>

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases, disorders of the central nervous system, addiction and immune-related diseases, including cancers. Our first drug product, OMIDRIA, is marketed in the United States (U.S.) for use during cataract surgery or intraocular lens replacement.

Basis of Presentation

Our condensed consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All intercompany transactions have been eliminated, and we have determined we operate in one segment. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of September 30, 2020 and December 31, 2019 and for the three and nine months ended September 30, 2020 and 2019 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2019 has been derived from our audited financial statements but does not include all of the information and footnotes required by GAAP for audited annual financial information.

The accompanying unaudited condensed consolidated financial statements and related notes thereto should be read in conjunction with the audited consolidated financial statements and related notes thereto that are included in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 2, 2020.

Risks and Uncertainties

In its 2021 outpatient prospective payment system (OPPS) proposed rule, the Centers for Medicare and Medicaid Services (CMS), a part of the Department of Health and Human Services (HHS), confirmed the October 1, 2020 expiration of pass-through reimbursement for OMIDRIA and indicated an intention to package payment for OMIDRIA with payment for the associated surgical procedure in both the hospital outpatient department (HOPD) and ambulatory surgery center (ASC) settings. We are continuing to pursue administrative and legislative avenues to secure separate payment for OMIDRIA; however, we cannot provide assurance that these efforts will be successful.

The outbreak of the novel strain of coronavirus (SARS-CoV-2) that causes COVID-19 and the responses to the global pandemic by various governmental authorities, the medical community and others continue to have a significant impact on our business. In March 2020, ASCs and hospitals using OMIDRIA postponed nearly all cataract surgery in response to recommendations from government and medical organizations. As a result, we did not record any sales of OMIDRIA to our wholesalers from March 25 to May 19, 2020. However, by the end of June 2020, the run rate of weekly OMIDRIA sales had recovered to levels approximating those seen prior to the pandemic. Due to the unknown magnitude, duration and outcome of the COVID-19 pandemic, it is not possible to estimate precisely its impact on our business, operations or financial results; however, the impact has been and could continue to be material.

As of September 30, 2020, we had cash, cash equivalents and short-term investments of \$153.5 million and an accounts receivable-based line of credit that allows us to borrow up to the lesser of \$50.0 million or 85% of our accounts receivable borrowing base, less certain reserves. We have incurred losses from operations of \$76.8 million for the nine months ended September 30, 2020, and cash used in operating activities was \$81.7 million for the nine months ended

September 30, 2020. We will continue to incur losses from operating activities until our revenues exceed operating costs and debt service obligations.

OMIDRIA pass-through reimbursement from CMS expired on October 1, 2020. If continued separate payment is determined not to be reasonably achievable in the near term, we have developed a commercial strategy that can be quickly implemented to lower the per-vial sales price of OMIDRIA to achieve substantially larger sales volumes. We believe that this approach would result in substantial revenues from OMIDRIA, in part because CMS Medicare Part B beneficiaries only represent approximately 45% of cataract surgery procedures annually.

We anticipate narsoplimab for HSCT-TMA will receive FDA approval and will launch in early to mid-2021. Currently we cannot fully predict the timing or the magnitude of narsoplimab revenues, but we believe they will be significant. Execution of our sales and marketing strategies for the launch of narsoplimab for HSCT-TMA is underway. These plans include various milestones at which we commit to incremental activities, providing for flexibility in the timing of costs incurred should the approval of narsoplimab be accelerated or delayed. If warranted, we will adjust the timing and associated costs of our HSCT-TMA launch activities as we advance through the biologics license application (BLA) review and approval process.

We plan to continue to fund our operations for at least the next twelve months with our cash and investments on hand, from sales of OMIDRIA and, if FDA approval is granted, from sales of narsoplimab for HSCT-TMA. There is also the possibility that we could generate revenue from sales of narsoplimab for the treatment of COVID-19. In addition, we may utilize funds available under our accounts receivable-based line of credit, which allows us to borrow up to 85% of our available accounts receivable borrowing base, less certain reserves, or \$50.0 million, whichever is less. Should it be necessary or determined to be strategically advantageous, we also could pursue debt financings, public and private offerings of our equity securities similar to those we have completed previously, or other strategic transactions, which may include licensing a portion of our existing technology. Should it be necessary to manage our operating expenses, we would reduce our projected cash requirements through reduction of our expenses by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant items subject to such estimates include revenue recognition, stock-based compensation expense and accruals for clinical trials, manufacturing of drug product and clinical drug supply and other contingencies. We base our estimates on historical experience and on various other factors, including the impact of the COVID-19 pandemic, that we believe are reasonable under the circumstances; however, actual results could differ from these estimates.

Revenue Recognition

When we enter into a customer contract, we perform the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation.

We generally record revenue from product sales when the product is delivered to our wholesalers. Product sales are recorded net of wholesaler distribution fees and estimated chargebacks, rebates, returns and purchase-volume discounts. Accruals or allowances are established for these deductions in the same period when revenue is recognized, and actual amounts incurred are offset against the applicable accruals or allowances. We reflect each of these accruals or allowances as either a reduction in the related accounts receivable or as an accrued liability depending on how the amount is expected to be settled.

Right-of-Use Assets and Related Lease Liabilities

We record operating leases as right-of-use assets and recognize the related lease liabilities equal to the fair value of the lease payments using our incremental borrowing rate when the implicit rate in the lease agreement is not readily available. We recognize variable lease payments when incurred. Costs associated with operating lease assets are recognized on a straight-line basis within operating expenses over the term of the lease. We record finance leases as a component of property and equipment and amortize these assets within operating expenses on a straight-line basis to their residual values over the shorter of the term of the underlying lease or the estimated useful life of the equipment. The interest component of a finance lease is included in interest expense and recognized using the effective interest method over the lease term. We account for leases with initial terms of 12 months or less as operating expenses on a straight-line basis over the lease term.

Advance Payments

Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and then recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. We recognize the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination. A valuation allowance is established when it is more likely than not that the deferred tax assets will not be realized.

Stock-Based Compensation

Stock-based compensation expense is recognized for all share-based payments based on estimated fair values as of the date of grant. The fair value of our stock options is calculated using the Black-Scholes option-pricing model which requires judgmental assumptions including volatility, forfeiture rates and expected option life. We use the straight-line method to allocate stock-based compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period.

Recently Adopted Pronouncements

In June 2016, the Financial Accounting Standards Board issued ASU 2016-13, *Financial Instruments—Credit Losses*, (Topic 326) which changes how entities account for credit losses on most financial assets and certain other instruments and expands disclosures. The standard is effective for annual and interim periods beginning after December 15, 2019 with early adoption permitted. We adopted the standard on January 1, 2020 and the adoption did not have a material impact on our consolidated financial statements and disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In August 2020, the Financial Accounting Standards Board issued ASU 2020-06, *Debt—Debt with Conversion Options* (Subtopic 470-20) and *Derivatives and Hedging—Contracts in Entity's Own Equity* (Subtopic 815-40), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. Among other changes, ASU 2020-06 removes from U.S. GAAP the liability and equity separation model for convertible instruments with a cash conversion feature, and as a result, after adoption, entities will no longer separately present in equity an embedded conversion feature for such debt. Similarly, the embedded conversion feature will no longer be amortized into income as interest expense over the life of the instrument. Instead, entities will account for a convertible debt instrument wholly as debt unless (1) a convertible instrument contains features that require bifurcation as a derivative under Topic 815, *Derivatives and Hedging*, or (2) a

convertible debt instrument was issued at a substantial premium. Among other potential impacts, this change is expected to reduce reported interest expense, increase reported net income, and result in a reclassification of certain conversion feature balance sheet amounts from stockholders' equity to liabilities as it relates to the Company's convertible senior notes. Additionally, ASU 2020-06 requires the application of the if-converted method to calculate the impact of convertible instruments on diluted earnings per share (EPS), which is consistent with the Company's accounting treatment under the current standard. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, with early adoption permitted for fiscal years beginning after December 15, 2020, and can be adopted on either a fully retrospective or modified retrospective basis. The Company is evaluating the impact of this pronouncement on its consolidated financial statements.

In December 2019, the Financial Accounting Standards Board issued ASU 2019-12, *Income Taxes* (Topic 740), which is intended to simplify various aspects of the income tax accounting guidance, including elimination of the exception to the incremental approach of intra-period tax allocation when there is a loss from continuing operations and income or gain from other items (for example, other comprehensive income). ASU 2019-12 is effective for public business entities for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is evaluating the impact of this pronouncement on its consolidated financial statements. We have a history of losses and therefore have historically not made a provision for income taxes.

Note 2—Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common share equivalents outstanding for the period, determined using the treasury-stock method. Common share equivalents are excluded from the diluted net loss per share computation if their effect is anti-dilutive.

The basic and diluted net loss per share amounts for the three and nine months ended September 30, 2020 and 2019 were computed based on the shares of common stock outstanding during the respective periods. Potentially dilutive securities excluded from the diluted loss per share calculation are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Outstanding options to purchase common stock	1,456,454	3,026,871	1,777,393	2,829,807
Outstanding warrants to purchase common stock	9,828	18,128	11,712	16,923
Total potentially dilutive shares excluded from loss per share	<u>1,466,282</u>	<u>3,044,999</u>	<u>1,789,105</u>	<u>2,846,730</u>

Note 3—Certain Balance Sheet Accounts

Accounts Receivable, net

Accounts receivable, net consist of the following:

	September 30, 2020	December 31, 2019
	(In thousands)	
Trade receivables, net	\$ 37,218	\$ 35,074
Sublease and other receivables	161	111
Total accounts receivables, net	<u>\$ 37,379</u>	<u>\$ 35,185</u>

Trade receivables as of September 30, 2020 are shown net of \$8.7 million of product return and chargeback allowances. Trade receivables as of December 31, 2019 are shown net of \$1.6 million of chargeback allowances.

Inventory

Inventory consists of the following:

	September 30, 2020	December 31, 2019
	(In thousands)	
Raw materials	\$ 79	\$ 91
Work-in-progress	797	338
Finished goods	666	718
Total inventory	<u>\$ 1,542</u>	<u>\$ 1,147</u>

Property and Equipment, Net

Property and equipment, net consists of the following:

	September 30, 2020	December 31, 2019
	(In thousands)	
Finance leases	\$ 5,690	\$ 5,474
Laboratory equipment	2,903	2,844
Computer equipment	985	921
Office equipment and furniture	625	625
Total cost	10,203	9,864
Less accumulated depreciation and amortization	(7,253)	(6,035)
Total property and equipment, net	<u>\$ 2,950</u>	<u>\$ 3,829</u>

Depreciation expense for the three months ended September 30, 2020 and 2019 was \$0.4 million for both periods, respectively. Depreciation expense for the nine months ended September 30, 2020 and 2019 was \$1.2 million and \$1.3 million, respectively.

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2020	December 31, 2019
	(In thousands)	
Sales rebates, fees and discounts	\$ 10,201	\$ 10,870
Contract research and development	8,813	24,107
Employee compensation	6,415	3,546
Consulting and professional fees	5,479	3,610
Interest payable	3,736	1,640
Clinical trials	1,482	1,982
Other accrued expenses	822	872
Total accrued expenses	<u>\$ 36,948</u>	<u>\$ 46,627</u>

Note 4—Fair-Value Measurements

As of September 30, 2020, and December 31, 2019, all investments were classified as short-term and available-for-sale on the accompanying Condensed Consolidated Balance Sheets. Investment income, which was included as a component of other income, consists of interest earned.

On a recurring basis, we measure certain financial assets at fair value. Fair value is defined 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. The accounting standard establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available. The following summarizes the three levels of inputs required:

Level 1—Observable inputs for identical assets or liabilities, such as quoted prices in active markets;

Level 2—Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3—Unobservable inputs in which little or no market data exists, therefore they are developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

Our fair value hierarchy for our financial assets and liabilities measured at fair value on a recurring basis are as follows:

	September 30, 2020			Total
	Level 1	Level 2	Level 3	
(In thousands)				
Assets:				
Money-market funds classified as non-current restricted investments	\$ 1,154	\$ —	\$ —	\$ 1,154
Money-market funds classified as short-term investments	132,448	—	—	132,448
Total	<u>\$ 133,602</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 133,602</u>
	December 31, 2019			Total
	Level 1	Level 2	Level 3	
(In thousands)				
Assets:				
Money-market funds classified as non-current restricted investments	\$ 1,154	\$ —	\$ —	\$ 1,154
Money-market funds classified as short-term investments	57,704	—	—	57,704
Total	<u>\$ 58,858</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 58,858</u>

Cash held in demand deposit accounts of \$21.1 million and \$3.1 million is excluded from our fair-value hierarchy disclosure as of September 30, 2020 and December 31, 2019, respectively. There were no unrealized gains or losses associated with our investments as of September 30, 2020 or December 31, 2019. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets for receivables, accounts payable, other current monetary assets and liabilities approximate fair value.

See “Note 6—Unsecured Convertible Senior Notes” for the carrying amount and estimated fair value of our 6.25% Convertible Senior Notes due 2023.

Note 5—Line of Credit

We have a Loan and Security Agreement with Silicon Valley Bank, which provides for a \$50.0 million revolving line of credit facility (the Line of Credit Agreement). Under the Line of Credit Agreement, we may draw, on a revolving basis, up to the lesser of \$50.0 million or 85.0% of our eligible accounts receivable, less certain reserves. Interest on amounts outstanding is payable monthly at the greater of 5.5% and the prime rate. The line of credit is secured by all our assets excluding intellectual property and development program inventories.

As of September 30, 2020 and December 31, 2019, we had no outstanding borrowings under the Line of Credit Agreement.

Note 6—Unsecured Convertible Senior Notes

Unsecured convertible senior notes outstanding at September 30, 2020 and December 31, 2019 are as follows:

	Balance as of September 30, 2020		
	2023 Notes	2026 Notes (In thousands)	Total
Principal amount	\$ 95,000	\$ 225,030	\$ 320,030
Unamortized discount	(18,276)	(62,591)	(80,867)
Unamortized issuance costs attributable to liability component	(1,583)	(4,772)	(6,355)
Total Convertible Senior Notes, net	<u>\$ 75,141</u>	<u>\$ 157,667</u>	<u>\$ 232,808</u>
Fair value of outstanding Convertible Senior Notes (2)	<u>\$ 89,775</u>	<u>\$ 182,043</u>	
Amount by which the Convertible Senior Notes if-converted value exceeds their principal amount	<u>\$ —</u>	<u>\$ —</u>	
Equity component	\$ 25,854	\$ 63,544	
Unamortized issuance costs	(837)	(1,916)	
Net carrying amount of equity component (1)	<u>\$ 25,017</u>	<u>\$ 61,628</u>	

	Balance as of December 31, 2019		
	2023 Notes	2026 Notes (In thousands)	Total
Principal amount	\$ 210,000	\$ —	\$ 210,000
Unamortized discount	(47,660)	—	(47,660)
Unamortized issuance costs attributable to liability component	(4,127)	—	(4,127)
Total Convertible Senior Notes, net	<u>\$ 158,213</u>	<u>\$ —</u>	<u>\$ 158,213</u>
Fair value of outstanding Convertible Senior Notes (2)	<u>\$ 208,163</u>	<u>\$ —</u>	
Amount by which the Convertible Senior Notes if-converted value exceeds their principal amount	<u>\$ —</u>	<u>\$ —</u>	
Equity component	\$ 57,152	\$ —	
Unamortized issuance costs	(1,851)	—	
Net carrying amount of equity component (1)	<u>\$ 55,301</u>	<u>\$ —</u>	

(1) Included in the condensed consolidated balance sheet within additional paid-in capital

(2) The fair value is classified as Level 3 due to the limited trading activity for the Convertible Senior Notes.

2023 Convertible Senior Notes

On November 15, 2018, we issued \$210.0 million in aggregate principal amount of our 6.25% Convertible Senior Notes (the 2023 Notes). The 2023 Notes are unsecured and accrue interest at an annual rate of 6.25% per annum, payable semi-annually in arrears on May 15 and November 15 of each year. The 2023 Notes mature on November 15, 2023 unless earlier purchased, redeemed or converted in accordance with their terms.

The 2023 Notes will be convertible into cash, shares of our common stock or a combination thereof, as we elect at our sole discretion. The initial conversion rate is 52.0183 shares of our common stock per \$1,000 of note principal (equivalent to an initial conversion price of approximately \$19.22 per share of common stock), subject to adjustment in certain circumstances. To reduce the dilutive impact or potential cash expenditure associated with conversion of the 2023 Notes, we entered into a capped call transaction (the 2023 Capped Call), which essentially covers the number of

shares of our common stock underlying the 2023 Notes when our common stock is trading between the initial conversion price of \$19.22 per share and \$28.84 per share.

On August 14, 2020, we issued \$210.0 million aggregate principal amount of 5.25% Convertible Senior Notes (the 2026 Notes) and used \$125.6 million of the net proceeds to repurchase \$115.0 million principal amount of the 2023 Notes (see “2026 Convertible Senior Notes” below). The settlement consideration was allocated between the repurchase of the liability and the equity component with the fair value of the liability component estimated to be \$103.6 million based on the expected future cash flows associated with the \$115.0 million principal amount discounted at a 9.9% effective interest rate. The remaining \$22.0 million was accounted for as a repurchase of the equity component, reducing additional paid-in capital. As of the repurchase date of August 14, 2020, the carrying value of the repurchased 2023 Notes, net of unamortized debt discount and issuance costs, was \$90.2 million. The difference between the \$103.6 million fair value of the 2023 Notes repurchased and the carrying value of \$90.2 million resulted in a \$13.4 million loss on early extinguishment of debt. After giving effect to the repurchase, the total principal amount outstanding on the 2023 Notes as of August 14, 2020 was \$95.0 million.

In connection with the repurchase of \$115.0 million in principal amount of the 2023 Notes, we entered into a capped call termination contract in August 2020 for approximately 6.0 million underlying shares to unwind a proportionate amount of the 2023 Capped Call. Upon settlement, the Company received \$7.5 million in cash and recorded a \$0.8 million loss due to the change in fair value of the contract between signing and settlement dates. The proceeds were recorded as an increase in additional paid-in capital and the loss was recorded to other expense in the condensed consolidated statements of operations and comprehensive loss. As of September 30, 2020, approximately 4.9 million shares remained outstanding on the 2023 Capped Call.

The following table sets forth total interest expense recognized in connection with the 2023 Notes:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
	(In thousands)			
Contractual interest expense	\$ 2,363	\$ 3,281	\$ 8,925	\$ 9,844
Amortization of debt issuance costs	156	188	567	543
Amortization of debt discount	1,804	2,167	6,551	6,271
Total	<u>\$ 4,323</u>	<u>\$ 5,636</u>	<u>\$ 16,043</u>	<u>\$ 16,658</u>

2026 Convertible Senior Notes

In August 2020, we issued \$210.0 million aggregate principal amount of 5.25% convertible senior notes. In September 2020, an additional \$15.0 million aggregate principal amount was issued on the partial exercise of the underwriters’ option, which resulted in an aggregate principal amount outstanding of \$225.0 million. The issuance of the notes and use of proceeds are below:

	<u>(In thousands)</u>
2026 Notes issued	\$ 225,030
Termination of the 2023 Capped Call contracts related to debt repurchased	7,549
Repurchase of 2023 Notes	(125,638)
Purchase of 2026 Capped Call	(23,223)
Issuance costs	(6,785)
Net proceeds available for corporate use	<u>\$ 76,933</u>

The 2026 Notes are unsecured and accrue interest at an annual rate of 5.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year. The 2026 Notes mature on February 15, 2026, unless earlier purchased, redeemed or converted in accordance with their terms.

The initial conversion rate is 54.0906 shares of our common stock per \$1,000 of note principal (equivalent to an initial conversion price of approximately \$18.4875 per share of common stock), which equals approximately 12.2 million shares upon conversion, subject to adjustment in certain circumstances.

The 2026 Notes are convertible at the option of the holders on or after November 15, 2025 at any time prior to the close of business on February 12, 2026, the second scheduled trading day immediately before the stated maturity date of February 15, 2026. Additionally, holders may convert their 2026 Notes at their option at specified times prior to the maturity date only if:

- (1) during any calendar quarter, beginning after September 30, 2020, that the last reported sale price per share of our common stock exceeds 130% of the conversion price of the 2026 Notes for each of at least 20 trading days in the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;
- (2) during the five consecutive business days immediately after any five-consecutive-trading-day period (such five-consecutive-trading-day period, the “measurement period”) in which the trading price per \$1,000 principal amount of 2026 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of our common stock on such trading day and the conversion rate on such trading day;
- (3) there is an occurrence of one or more certain corporate events or distributions of our common stock; or
- (4) we call the 2026 Notes for redemption.

We may elect, at our sole discretion, to convert the 2026 Notes into cash, shares of our common stock or a combination thereof.

Subject to the satisfaction of certain conditions, we may redeem in whole or in part the 2026 Notes at our option beginning August 15, 2023 through the 50th scheduled trading day immediately before the maturity date at a cash redemption price equal to the principal amount of the 2026 Notes to be redeemed plus any accrued and unpaid interest to, but excluding, the redemption date. The 2026 Notes are subject to redemption only if certain requirements are satisfied, including that the last reported sale price per share of our common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date we send the related redemption notice and (ii) the trading day immediately before the date we send such notice.

In order to reduce the dilutive impact or potential cash expenditure associated with the conversion of the 2026 Notes, we entered into capped call transactions in connection with the initial issuance of the 2026 Notes and at the time of the issuance of additional 2026 Notes upon the underwriters’ partial exercise of their option (collectively, the 2026 Capped Call). The 2026 Capped Call will cover, subject to anti-dilution adjustments substantially similar to those applicable to the 2026 Notes, the number of shares of common stock underlying the 2026 Notes when our common stock is trading within the range of approximately \$18.49 and \$26.10. However, should the market price of our common stock exceed the \$26.10 cap, then the conversion of the 2026 Notes would have a dilutive impact or may require a cash expenditure to the extent the market price exceeds the cap price. The 2026 Capped Call will expire on various dates over the 50-trading-day period ranging from December 2, 2025 to February 12, 2026, if not exercised earlier. The 2026 Capped Call is a separate transaction and not part of the terms of the 2026 Notes and was executed separately from the issuance of the 2026 Notes. The amount paid for the 2026 Capped Call was recorded as a reduction to additional paid-in capital in the condensed consolidated balance sheet.

We evaluated the accounting for the issuance of the 2026 Notes and concluded that the embedded conversion features meet the requirements for a derivative scope exception for instruments that are both indexed to an entity’s own stock and classified in stockholders’ equity in its balance sheet, and that the cash conversion guidance applies. Therefore, proceeds of \$225.0 million are allocated first to the liability component based on the fair value of non-convertible debt with the residual proceeds allocated to the equity component for the conversion features. The Company

allocated \$6.8 million in issuance costs associated with the 2026 Notes to the liability and equity component in the same proportion as the \$225.0 million in proceeds.

Further, we concluded the 2026 Capped Call qualifies for a derivative scope exception for instruments that are both indexed to an entity's own stock and classified in stockholders' equity in its balance sheet. Consequently, the fair value of the 2026 Capped Call of \$23.2 million is classified as equity and will not be subsequently remeasured.

In accounting for the issuance of the 2026 Notes, we separated the 2026 Notes into liability and equity components, using an effective interest rate of 12.5% to determine the fair value of the liability component.

The following table sets forth interest expense recognized related to the 2026 Notes:

	Three and Nine Months Ended September 30, 2020
	(In thousands)
Contractual interest expense	\$ 1,444
Amortization of debt issuance costs	74
Amortization of debt discount	976
Total	<u>\$ 2,494</u>

Future minimum payments for the 2023 and 2026 Notes as of September 30, 2020 are as follows:

	(In thousands)
2020	\$ —
2021	—
2022	—
2023	95,000
2024	—
2025 and thereafter	225,030
Total future minimum payments under the convertible senior notes	<u>\$ 320,030</u>

Note 7—Leases

We have operating leases related to our office and laboratory space and finance leases for certain laboratory and office equipment as follows:

	September 30, 2020	December 31, 2019
	(In thousands)	
Assets		
Operating lease assets	\$ 26,116	\$ 27,082
Finance lease assets, net	2,150	2,973
Total lease assets	<u>\$ 28,266</u>	<u>\$ 30,055</u>
Liabilities		
Current:		
Operating leases	\$ 2,619	\$ 2,282
Finance leases	1,135	1,222
Non-current:		
Operating leases	28,767	30,772
Finance leases	950	1,546
Total lease liabilities	<u>\$ 33,471</u>	<u>\$ 35,822</u>

The components of total lease cost are as follows:

	Nine Months Ended September 30,	
	2020	2019
(In thousands)		
Lease cost		
Operating lease cost	\$ 4,540	\$ 3,121
Finance lease cost:		
Amortization	1,039	984
Interest	224	248
Variable lease cost	1,715	1,699
Sublease income	(929)	(673)
Total lease cost	<u>\$ 6,589</u>	<u>\$ 5,379</u>

The supplemental cash flow information related to leases is as follows:

	Nine Months Ended September 30,	
	2020	2019
(In thousands)		
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows used for operating leases	\$ 6,490	\$ 4,962
Operating cash flows used for finance leases	\$ 224	\$ 248
Financing cash flows used for finance leases	\$ 889	\$ 813

Note 8—Commitments and Contingencies

Lease Agreements

We lease our office and laboratory space in The Omeros Building under a lease agreement with BMR - 201 Elliott Avenue LLC. The initial term of the lease ends in November 2027, and we have two options to extend the lease term, each by five years. As of September 30, 2020, the remaining aggregate non-cancelable rent payable under the initial term of the lease, excluding common area maintenance and related operating expenses, is \$48.2 million.

Contracts

We have various agreements with third parties that would collectively require payment of termination fees totaling \$35.9 million if we had cancelled the work as of September 30, 2020.

Development Milestones and Product Royalties

We have licensed a variety of intellectual property from third parties that we are currently developing or may develop in the future. These licenses may require milestone payments in connection with clinical development or commercial milestones and/or low single to low double-digit royalties on the net income or net sales of the product. For the three and nine months ended September 30, 2020 and 2019, development milestones were insignificant. We do not owe any royalties on OMIDRIA.

Note 9—Shareholders' Deficit

Common Stock and Warrants

For the nine months ended September 30, 2020, we received proceeds of \$5.0 million upon the exercise of stock options which resulted in the issuance of 550,342 shares of common stock. For the nine months ended September 30,

2019, we received proceeds of \$5.0 million upon the exercise of stock options which resulted in the issuance of 513,790 shares of common stock.

As of September 30, 2020 and December 31, 2019, we had 243,115 warrants outstanding with a weighted average exercise price of \$20.68 per share.

Underwritten Public Offering of Common Stock

On August 14, 2020, we sold 6.9 million shares of our common stock at a public offering price of \$14.50 per share. After deducting underwriter discounts and offering expenses, we received net proceeds from the transaction of \$93.7 million.

Interim Condensed Consolidated Statements of Shareholders' Deficit

The changes in interim balances of the components of our shareholders' deficit are as follows:

	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
	(In thousands)			
Balance January 1, 2020	\$ 542	\$ 625,048	\$ (734,611)	\$ (109,021)
Exercise of stock options	3	2,709	—	2,712
Stock-based compensation expense	—	3,476	—	3,476
Net loss	—	—	(29,031)	(29,031)
Balance March 31, 2020	545	631,233	(763,642)	(131,864)
Exercise of stock options	—	66	—	66
Stock-based compensation expense	—	3,822	—	3,822
Net loss	—	—	(33,294)	(33,294)
Balance June 30, 2020	545	635,121	(796,936)	(161,270)
Issuance of common stock in direct offering, net of offering costs	69	93,606	—	93,675
Exercise of stock options	2	2,198	—	2,200
Stock-based compensation expense	—	3,824	—	3,824
Equity component of 2026 Notes, net of issuance costs	—	61,628	—	61,628
Purchases of 2026 Capped Calls	—	(23,223)	—	(23,223)
Equity component of early extinguishment of 2023 Notes	—	(22,073)	—	(22,073)
Termination of the 2023 Capped Call contracts related to debt repurchased	—	8,387	—	8,387
Tax benefit related to issuance of 2026 Notes, net of extinguishment	—	(12,011)	—	(12,011)
Net loss	—	—	(38,463)	(38,463)
Balance September 30, 2020	<u>\$ 616</u>	<u>\$ 747,457</u>	<u>\$ (835,399)</u>	<u>\$ (87,326)</u>

	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
	(In thousands)			
Balance January 1, 2019	\$ 490	\$ 549,479	\$ (650,125)	\$ (100,156)
Exercise of stock options	—	108	—	108
Stock-based compensation expense	—	3,374	—	3,374
Net loss	—	—	(24,345)	(24,345)
Balance March 31, 2019	490	552,961	(674,470)	(121,019)
Exercise of stock options	2	1,598	—	1,600
Stock-based compensation expense	—	3,598	—	3,598
Net loss	—	—	(14,453)	(14,453)
Balance June 30, 2019	492	558,157	(688,923)	(130,274)
Exercise of stock options	3	3,323	—	3,326
Stock-based compensation expense	—	3,496	—	3,496
Net loss	—	—	(16,463)	(16,463)
Balance September 30, 2019	<u>\$ 495</u>	<u>\$ 564,976</u>	<u>\$ (705,386)</u>	<u>\$ (139,915)</u>

Note 10—Stock-Based Compensation

Stock-based compensation expense is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(In thousands)			
Research and development	\$ 1,636	\$ 1,558	\$ 4,714	\$ 4,698
Selling, general and administrative	2,188	1,938	6,408	5,770
Total	<u>\$ 3,824</u>	<u>\$ 3,496</u>	<u>\$ 11,122</u>	<u>\$ 10,468</u>

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were applied to all stock option grants:

	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020
Estimated weighted-average fair value	\$ 8.21	\$ 8.22
Weighted-average assumptions:		
Expected volatility	82 %	77 %
Expected term, in years	6.1	6.0
Risk-free interest rate	0.58 %	1.10 %
Expected dividend yield	— %	— %

Stock option activity for all stock plans and related information is as follows:

	<u>Options Outstanding</u>	<u>Weighted- Average Exercise Price per Share</u>	<u>Remaining Contractual Life (In years)</u>	<u>Aggregate Intrinsic Value (In thousands)</u>
Balance at December 31, 2019	11,207,931	\$ 11.72		
Granted	2,074,460	12.36		
Exercised	(550,342)	9.05		
Forfeited	(635,433)	11.29		
Balance at September 30, 2020	<u>12,096,616</u>	<u>\$ 11.98</u>	<u>6.2</u>	<u>\$ 3,433</u>
Vested and expected to vest at September 30, 2020	<u>11,689,261</u>	<u>\$ 11.93</u>	<u>6.1</u>	<u>\$ 3,432</u>
Exercisable at September 30, 2020	<u>8,407,551</u>	<u>\$ 11.38</u>	<u>5.1</u>	<u>\$ 3,426</u>

As of September 30, 2020, there were 3.7 million unvested options outstanding that will vest over a weighted-average period of 2.6 years and 4.0 million shares were available to grant. The total estimated compensation expense yet to be recognized on outstanding options is \$28.0 million.

Note 11—Income Taxes

We have a history of losses and therefore have historically not made a provision for income taxes. However, in the quarter ended September 30, 2020, we recorded an income tax benefit of \$7.9 million related to the issuance of our 2026 Notes (see “Note 6—Unsecured Convertible Senior Notes”). In accordance with intra-period tax allocation rules, the deferred tax liability related to the equity component of convertible debt is a source of income that can be used to recognize the tax benefit of the current year loss through continuing operations. The tax benefit related to the issuance of our 2026 Notes will not recur in subsequent years. Deferred income taxes reflect the tax effect of net operating loss and tax credit carryforwards and the net temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases, disorders of the central nervous system, and immune-related diseases, including cancers.

Our drug product OMIDRIA[®] is marketed in the United States for use during cataract surgery or intraocular lens replacement for adult and pediatric patients. Our drug candidate narsoplimab is the subject of a rolling biologics license application ("BLA") with the U.S. Food and Drug Administration ("FDA") for narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy ("HSCT-TMA"), which will be submitted in mid-November. We also have multiple Phase 3 and Phase 2 clinical-stage development programs in our pipeline, which are focused on: complement-mediated disorders, including Immunoglobulin A ("IgA") nephropathy and atypical hemolytic uremic syndrome ("aHUS"), as well as addiction. We also initiated a Phase 1 clinical program for our MASP-3 inhibitor OMS906 targeting the alternative pathway of complement. In addition, we have a diverse group of preclinical programs, including GPR174, a novel target in immuno-oncology that modulates a new cancer immunity axis that we recently discovered. Small-molecule inhibitors of GPR174 are part of our proprietary G protein-coupled receptor ("GPCR") platform through which we control 54 new GPCR drug targets and their corresponding compounds. We also exclusively possess a novel antibody-generating platform. We have retained control of all commercial rights for OMIDRIA and each of our product candidates and programs.

OMIDRIA Separate Payment

As of October 1, 2020, OMIDRIA pass-through status expired. We are currently seeking separate payment for OMIDRIA through administrative and legislative means as more fully described under "Commercial Product—OMIDRIA" below.

Impact of Global Pandemic

The outbreak of the novel strain of coronavirus (SARS-CoV-2), which causes COVID-19, and the responses to the global pandemic by various governmental authorities, the medical community and others continue to have a significant impact on our business. In March 2020, ambulatory surgery centers ("ASCs") and hospitals using OMIDRIA postponed nearly all cataract surgery in response to recommendations from government and medical organizations. As a result, we did not record any sales of OMIDRIA to our wholesalers from March 25 to May 19, 2020. However, by the end of June 2020, the run rate of weekly OMIDRIA sales had recovered to levels approximating those seen prior to the pandemic. COVID-19 and the corresponding government response could have a continuing adverse impact on our business, operations and financial results. If the number of cataract procedures once again becomes limited, either by a need for time-consuming safety protocols, reduction in patient demand, or prohibition on elective surgical procedures in some localities, then we would expect a corresponding reduction in demand for OMIDRIA. Additionally, new or continued restrictions on visits to customer facilities by our field sales representatives could lead to a further reduction in our OMIDRIA revenues. Due to the unknown magnitude, duration and outcome of the COVID-19 pandemic, especially in light of the variances both in the severity of and in the local governmental responses to the COVID-19 pandemic across the U.S., it is not possible to estimate precisely its impact on our business, operations or financial results; however, the impact has been and could continue to be material.

Commercial Product - OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%

OMIDRIA is approved by the FDA for use during cataract surgery or intraocular lens replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. Outside the U.S., we have received approval from the European Commission (“EC”) to market OMIDRIA in the European Economic Area (“EEA”) for use during cataract surgery and other IOL replacement procedures for maintenance of intraoperative mydriasis (pupil dilation), prevention of intraoperative miosis and reduction of acute postoperative ocular pain.

OMIDRIA is a proprietary drug product containing two active pharmaceutical ingredients: ketorolac, an anti-inflammatory agent, and phenylephrine, a mydriatic, or pupil dilating, agent. Cataract and other lens replacement surgery involves replacement of the original lens of the eye with an artificial intraocular lens. OMIDRIA is added to standard irrigation solution used during cataract and lens replacement surgery and is delivered intracamerally, or within the anterior chamber of the eye, to the site of the surgical trauma throughout the procedure. Preventing pupil constriction is essential for these procedures and, if miosis occurs, the risk of damaging structures within the eye and other complications increases, as does the operating time required to perform the procedure.

We launched OMIDRIA in the U.S. in the second quarter of 2015 and sell OMIDRIA primarily through wholesalers who, in turn, sell to ASCs and hospitals. The Centers for Medicare & Medicaid Services (“CMS”), a part of the Department of Health and Human Services (“HHS”) and the federal agency responsible for administering the Medicare program, granted transitional pass-through reimbursement status for OMIDRIA in 2014, effective from January 1, 2015 through December 31, 2017. Pass-through status allows for separate payment (i.e., outside the packaged payment rate for the surgical procedure) under Medicare Part B. In March 2018, Congress extended pass-through reimbursement status for a small number of drugs, including OMIDRIA, used during procedures performed on Medicare Part B fee-for-service patients through September 30, 2020.

In its 2021 outpatient prospective payment system (“OPPS”) proposed rule, CMS confirmed the October 1, 2020 expiration of pass-through reimbursement for OMIDRIA and indicated an intention to package payment for OMIDRIA with payment for the associated surgical procedure in both the hospital outpatient department and ASC settings. In September 2020, we submitted to CMS a comment letter on the 2021 OPPS proposed rule and a legal memorandum outlining our position that OMIDRIA meets all of the regulatory criteria established by CMS for separate payment in the ASC setting. CMS is required under the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act to review OPPS payments for opioids and evidence-based non-opioid alternatives for pain management with a goal to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives, and in 2019 it codified revisions to the ASC payment system pursuant to its policy to “unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting.” CMS continued this policy, without change, in 2020 and has proposed to extend it again in 2021. During the time that these revisions to the ASC payment system have been in force, they have not applied to OMIDRIA because OMIDRIA has had pass-through status and, accordingly, has not been separately packaged. OMIDRIA does not contain an opioid, has an FDA-approved label indication for postoperative pain reduction and CMS considers the drug to function as a surgical supply. Because OMIDRIA is subject to packaged payment following expiration of its pass-through status, we believe that OMIDRIA now satisfies the criteria for separate payment when provided in the ASC setting and that CMS is required to comply with regulatory law and pay separately for OMIDRIA in the ASC setting. Although we can provide no assurance regarding whether or when separate payment for OMIDRIA in the ASC setting will be effective, if we are successful in securing separate payment for OMIDRIA for the fourth quarter of 2020, we expect that OMIDRIA will receive similar separate payment in the ASC setting throughout 2021. We also are continuing to pursue other administrative and legislative avenues to secure separate payment for OMIDRIA for the remainder of 2020 and beyond; however, we cannot provide assurance that these efforts will be successful.

If continued separate payment is determined not to be reasonably achievable in the near term, we have developed a commercial strategy that can be quickly implemented to lower the per-vial sales price of OMIDRIA to achieve substantially larger sales volumes. We believe that this approach would result in substantial revenues from sales of OMIDRIA, in part because CMS Medicare Part B beneficiaries only represent approximately 45% of cataract surgery

procedures annually. However, we are likely to have significantly reduced sales of OMIDRIA until we are able to implement such strategy. For more information regarding OMIDRIA reimbursement, see “Financial Summary” below.

In July 2018, we placed OMIDRIA on the market in the European Union (“EU”) on a limited basis and continue to maintain the ongoing validity of the Marketing Authorization for OMIDRIA in Europe. At this time, we do not expect to see significant sales of OMIDRIA in any countries within the EEA or other international territories.

Clinical Development Programs

Our clinical stage development programs include:

- MASP-2 - narsoplimab (OMS721) - Lectin Pathway Disorders. Narsoplimab, also referred to as OMS721, is our lead fully human monoclonal antibody targeting monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (“MASP-2”), a novel pro-inflammatory protein target involved in activation of the lectin pathway of complement. The lectin pathway plays a role in the body’s inflammatory response and becomes activated as a result of tissue damage or trauma or microbial pathogen invasion. Inappropriate or uncontrolled activation of the lectin pathway can cause serious diseases and disorders. MASP-2 is the effector enzyme of the lectin pathway of the complement system, and the current development focus for narsoplimab is diseases that are strongly associated with activation of the lectin pathway.

We have completed our pivotal clinical trial for narsoplimab in HSCT-TMA, and Phase 3 clinical programs are underway for narsoplimab in IgA nephropathy and aHUS.

Narsoplimab has received multiple designations from the FDA and from the EMA across the three current indications. These include:

- HSCT-TMA: In the U.S., the FDA has granted narsoplimab (1) breakthrough therapy designation in patients who have persistent TMA despite modification of immunosuppressive therapy, (2) orphan drug designation for the prevention (inhibition) of complement-mediated TMAs, and (3) orphan drug designation for the treatment of HSCT-TMA. The EC also granted narsoplimab a designation as an orphan medicinal product for treatment in hematopoietic stem cell transplantation.
- IgA nephropathy: In the U.S., narsoplimab has received from the FDA (1) breakthrough therapy designation for the treatment of IgA nephropathy and (2) orphan drug designation in IgA nephropathy. In Europe, narsoplimab has designation as an orphan medicinal product for the treatment of primary IgA nephropathy.
- aHUS: In the U.S., narsoplimab has received from the FDA (1) fast-track designation for the treatment of patients with aHUS and (2) orphan drug designation for the prevention (inhibition) of complement-mediated thrombotic microangiopathies.

We plan to complete in mid-November the submission to FDA of our rolling BLA for narsoplimab for the treatment of HSCT-TMA, a frequently lethal complication of HSCT. A rolling submission enables us to submit sections of the BLA as they are completed, which can accelerate the time to approval by allowing FDA to review completed sections of the application as they are submitted rather than waiting for the entire BLA to be received before beginning its review. The nonclinical sections, including pharmacology, pharmacokinetics and toxicology data, and the chemistry, manufacturing and controls (“CMC”) sections for narsoplimab have already been submitted.

In October 2020, we reported the final clinical data from our pivotal trial of narsoplimab in HSCT-TMA, which are included in our BLA. The single-arm, open-label trial included safety and efficacy endpoints that were previously agreed with FDA. The efficacy endpoints were assessed for (1) all 28 patients who received at least one dose of narsoplimab and (2) patients who received the protocol-specified dosing of at least four weeks of narsoplimab.

The primary efficacy endpoint in the trial was the proportion of patients who achieved designated “responder” status based on improvement in HSCT-TMA laboratory markers and clinical status. This is referred to as the “complete response rate.” The primary laboratory markers that were evaluated were platelet count and lactate dehydrogenase (“LDH”), levels, while improvement in clinical status was evaluated based on organ function and transfusions. Patients were required to show improvement in both laboratory markers and clinical status to be considered a responder. All others were considered non-responders.

The FDA-agreed efficacy threshold for the primary endpoint is a complete response rate of 15%, meaning that a lower bound of the 95% confidence interval on the observed response rate greater than 15% is sufficient evidence of efficacy of narsoplimab in the treatment of the targeted patient population. Among patients who received at least one dose of narsoplimab, the complete response rate was 61% ($p < 0.0001$), while the complete response rate among patients who received the protocol-specified narsoplimab treatment of at least four weeks of dosing was 74% ($p < 0.0001$). The lower limit of the 95% confidence interval for both groups is a multiple of the 15% efficacy threshold.

Secondary endpoints in the trial were survival rates and change from baseline in HSCT-TMA laboratory markers. Among all treated patients, 68% survived for at least 100 days following HSCT-TMA diagnosis, while 83% of patients who received treatment for at least four weeks and 94% of the responders achieved this endpoint. Median overall survival was 274 days among all patients and 361 days among patients who received the protocol-specified treatment of at least four weeks. Median survival could not be estimated for responders because more than half of the responders were alive at last follow-up. Results also included statistically significant improvements in platelet count, LDH and haptoglobin. The treated population had multiple high-risk features that portend a poor outcome, including the persistence of HSCT-TMA despite modification of immunosuppression (which was a criterion for entry into the trial), graft-versus-host disease, significant infections, non-infectious pulmonary complications and neurological findings. The most common adverse events observed in the trial were nausea, vomiting, diarrhea, hypokalemia, neutropenia and fever, which are all common in stem-cell transplant patients. Six deaths occurred during the trial. These were due to sepsis, progression of the underlying disease, and graft-versus-host disease. All of these are common causes of death in this patient population.

In Europe, EMA has confirmed narsoplimab’s eligibility for EMA’s centralized review of a single MAA that, if approved, authorizes the product to be marketed in all EU member states and EEA countries. We are targeting to complete our MAA submission in 2021.

In our IgA nephropathy program, patient enrollment continues in the narsoplimab Phase 3 clinical trial, ARTEMIS-IGAN. The single Phase 3 trial design is a randomized, double-blind, placebo-controlled multicenter trial in patients at least 18 years of age with biopsy-confirmed IgA nephropathy and with 24-hour urine protein excretion greater than one gram per day at baseline on optimized renin-angiotensin system blockade. This trial includes a run-in period. Initially, patients are expected to receive an IV dose of study drug each week for 12 weeks; additional weekly dosing can be administered to achieve optimal response. The primary endpoint, which we believe could suffice for full or accelerated approval depending on the effect size, is reduction in proteinuria at 36 weeks after the start of dosing. The trial is designed to allow intra-trial adjustment in sample size. For the purposes of safety and efficacy assessments, the initial sample size for the proteinuria endpoint is estimated at 140 patients in each of the treatment and placebo groups. This will include a subset of patients with high levels of proteinuria (i.e., equal to or greater than 2 g/day) at baseline, and a substantial improvement at 36 weeks in this subset of patients alone could potentially form the basis for approval. We believe that the trial design will allow assessment for either full or accelerated approval at 36 weeks based on proteinuria results either (1) across the general population of study patients or (2) in the high-proteinuria subset of patients.

The Phase 3 clinical program in patients with aHUS, in which patient enrollment is ongoing, consists of one Phase 3 clinical trial – a single-arm (i.e., no control arm), open-label trial in patients with newly diagnosed or ongoing aHUS. This trial is targeting approximately 40 patients for full approval in Europe and accelerated approval in the U.S. with approximately 80 total patients required by FDA for full approval in the U.S.

- *Compassionate Use of Narsoplimab in COVID-19 Patients.* In March 2020, in response to a request from physicians at the Papa Giovanni XXIII Hospital in Bergamo, Italy, we initiated a compassionate use program for narsoplimab to treat COVID-19 patients with ARDS, a severe and life-threatening component of COVID-19.

The study included a total of six COVID-19 patients treated with narsoplimab under compassionate use, all with ARDS and requiring continuous positive airway pressure (CPAP) or intubation. At baseline, circulating endothelial cell (CEC) counts and serum levels of interleukin-6 (IL-6), interleukin-8 (IL-8), C-reactive protein (CRP), lactate dehydrogenase (LDH), D-dimer and aspartate aminotransferase (AST) were markedly elevated. During the course of the study, institutional guidelines at the treating hospital were updated to require that all COVID-19 patients in the hospital receive steroids. One patient treated with narsoplimab did not receive steroids. Of the five narsoplimab-treated patients who received steroids, two initiated them after already improving such that CPAP was no longer required or was discontinued the following day. The study evaluated CEC counts in a separate group of four patients receiving only steroids for a short duration, and the counts were found to be unaffected by steroid administration. This suggests that any beneficial effect of steroids on COVID-19-associated endothelial damage may be delayed and had little effect on the recovery course of the narsoplimab-treated patients who initiated steroid treatment after improving.

Narsoplimab treatment was associated with rapid and sustained reduction across all of these markers of endothelial damage and inflammation. In addition, massive bilateral pulmonary thromboses, seen in two of the patients, resolved while on narsoplimab. All six narsoplimab-treated patients recovered, survived and were discharged. Narsoplimab was well tolerated in the study and no adverse drug reactions were reported. Two control groups with similar baseline characteristics were used for retrospective comparison, both showing substantial mortality rates of 32% and 53%. A manuscript detailing the results of the study evaluating narsoplimab in patients with severe COVID-19 was published in the peer-reviewed journal *Immunobiology*.

Endothelial damage and resultant thromboses are significant to the pathophysiology of COVID-19, and we believe these data illustrate the importance of inhibiting the lectin pathway to treat critically ill COVID-19 patients. Endothelial damage activates the lectin pathway of complement. We believe the results observed following narsoplimab treatment in severe COVID-19 patients with ARDS at Papa Giovanni were consistent with those seen in HSCT-TMA and underscore the pathophysiologic similarities between these two disorders. Narsoplimab has been shown to inhibit lectin pathway activation and to block the MASP-2-mediated conversion of prothrombin to thrombin, microvascular injury-associated thrombus formation and the activation of factor XII as well as the MASP-2-mediated activation of kallikrein. We believe that the anticoagulant effects of narsoplimab may provide therapeutic benefits in both HSCT-TMA and COVID-19.

Following treatment of the initial six patients under the compassionate use study in Italy, we have continued compassionate-use treatment in the U.S. and Italy. Our discussions regarding the use of narsoplimab in COVID-19 have progressed with leaders across various government agencies. We have also received requests and are in discussions to include narsoplimab in platform trials for COVID-19.

- *MASP-3 - OMS906 - Alternative Pathway Disorders.* As part of our MASP program, we have identified mannan-binding lectin-associated serine protease-3 (“MASP-3”), which has been shown to be the key activator of the complement system’s alternative pathway (“APC”), and we believe that we are the first to make this and related discoveries associated with the APC. The complement system is part of the immune system’s innate response, and the APC is considered the amplification loop within the complement system. MASP-3 is responsible for the conversion of pro-factor D to factor D; converted factor D is necessary for the activation of the APC. Based on our alternative pathway-related discoveries, we have expanded our intellectual property position to protect our inventions stemming from these discoveries beyond MASP-2-associated inhibition of the lectin pathway to include inhibition of the alternative pathway. Our current primary focus in this program is developing MASP-3 inhibitors for the treatment of disorders related to the APC. We believe that MASP-3 inhibitors have the potential to treat patients suffering from a wide range of diseases and conditions, including: paroxysmal nocturnal hemoglobinuria (“PNH”); C3 glomerulopathy; multiple sclerosis; arthritis; traumatic brain injury; neuromyelitis optica; pauci-immune necrotizing crescentic glomerulonephritis; disseminated

intravascular coagulation; age-related macular degeneration; asthma; dense deposit disease; Behcet's disease; aspiration pneumonia; TMA; ischemia-reperfusion injury; Guillain Barre syndrome; Alzheimer's disease; amyotrophic lateral sclerosis; systemic lupus erythematosus; diabetic retinopathy; uveitis; chronic obstructive pulmonary disease; transplant rejection; acute respiratory distress syndrome; antineutrophil cytoplasmic antibody-associated vasculitis; anti-phospholipid syndrome; atherosclerosis; myasthenia gravis and others. Our OMS906 monoclonal antibody program has generated positive data in a well-established animal model associated with PNH, as well as strong pharmacodynamic activity in non-human primates. The program has also generated positive data in a well-established animal model of arthritis.

In August 2020, we submitted to FDA an Investigational New Drug Application ("IND") to initiate clinical trials evaluating OMS906, our lead human monoclonal antibody from our MASP-3 program, in the U.S. In September 2020 we began enrollment and dosing in a placebo-controlled, double-blind, single-ascending-dose and multiple-ascending-dose Phase 1 clinical trial to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of OMS906. Dosing is complete in the first cohort and has started in the second cohort of this Phase 1 trial. The third and fourth cohorts are currently enrolling. Initial data from the Phase 1 trial are expected next year.

- PDE7 - OMS527. In our phosphodiesterase 7 ("PDE7") program, we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders. In September 2019 we reported positive results from our Phase 1 single-ascending- and multiple-ascending-dose clinical trial designed to assess safety, tolerability and pharmacokinetics of our lead compound in healthy subjects.

In the double blind, randomized Phase 1 study, the study drug, referred to as OMS182399, met the primary endpoints of safety and tolerability and showed a favorable and dose-proportional pharmacokinetic profile supporting once-daily dosing. There was no apparent food effect on plasma exposure to OMS182399. Our focus is nicotine addiction, and we are planning our Phase 2 development program. Initiation of a Phase 2 study in our PDE7 program is dependent on availability of financial and other resources, which are currently prioritized for other programs.

Preclinical Development Programs and Platforms

Our preclinical programs and platforms include:

- Other MASP Inhibitor Preclinical Programs. We have generated positive preclinical data from MASP-2 inhibition in *in vivo* models of age-related macular degeneration, myocardial infarction, diabetic neuropathy, stroke, traumatic brain injury, ischemia-reperfusion injury, and other diseases and disorders. We are also developing a longer-acting second generation antibody targeting MASP-2, which we are targeting for initiation of clinical trials in early 2022. This program is designated as "OMS1029." Development efforts are also directed to a small-molecule inhibitor of MASP-2 designed for oral administration, as well as small-molecule inhibitors of MASP-3 and bispecific small- and large-molecule inhibitors of MASP-2/-3.
- GPR174 and GPCR Platform. We have developed a proprietary cellular redistribution assay which we use in a high-throughput manner to identify synthetic ligands, including antagonists, agonists and inverse agonists, that bind to and affect the function of orphan GPCRs. We have screened Class A orphan GPCRs against our small-molecule chemical libraries using the cellular redistribution assay and have identified and confirmed compounds that interact with 54 of the 81 Class A orphan GPCRs linked to a wide range of indications including cancer as well as metabolic, cardiovascular, immunologic, inflammatory and central nervous system disorders. One of our priorities in this program is GPR174, which is involved in the modulation of the immune system. In *ex vivo* human studies, our small-molecule inhibitors targeting GPR174 upregulate the production of cytokines, block multiple checkpoints and tumor promoters, and suppress regulatory T-cells. Based on our data, we believe that GPR174 controls a major pathway in cancer and modulation of the receptor could provide a seminal advance in immuno-oncologic treatments for a wide range of tumors. Our studies in mouse models of melanoma and colon carcinoma found that GPR174-deficiency resulted in significantly reduced tumor growth and improved survival of the animals versus normal mice. Our recent discoveries suggest a new approach to

cancer immunotherapy that targets inhibition of GPR174 and can be combined with and significantly improve the tumor-killing effects of adenosine pathway inhibitors and/or checkpoint inhibitors. These discoveries include (1) identification of cancer-immunity pathways controlled by GPR174, (2) the identification of phosphatidylserine as a natural ligand for GPR174, (3) a collection of novel small-molecule inhibitors of GPR174 and (4) a synergistic enhancement of “tumor-fighting” cytokine production by T cells following the combined inhibition of both GPR174 and the adenosine pathway (e.g., A2A and/or A2B), another key metabolic pathway that regulates tumor immunity. We continue to focus on GPR174 and several other of our GPCR targets with the objective of moving compounds targeting them into human trials.

Financial Summary

We recognized net losses of \$38.5 million and \$16.5 million for the three months ended September 30, 2020 and 2019, respectively, and our OMIDRIA revenues were \$26.1 million and \$29.9 million for the same periods. During the three months ended September 30, 2020, we recorded a \$13.4 million loss on early extinguishment of debt and a related tax benefit of \$7.9 million associated with the repurchase of \$115.0 million principal amount of our 6.25% Convertible Senior Notes (the “2023 Notes”). As of September 30, 2020, we had \$153.5 million in cash and cash equivalents and short-term investments available for general corporate use and \$37.4 million in accounts receivable, net.

We expect our net losses will continue until such time as we derive sufficient revenues from sales of OMIDRIA, narsoplimab and/or other sources, such as licensing, product sales and other revenues from our product candidates including narsoplimab for HSCT-TMA, that are sufficient to cover our operating expenses and debt service obligations.



- * Fiscal quarters without pass-through reimbursement
- ** Fiscal quarters with reduced cataract procedures due to COVID-19
- *** Pass-through reimbursement expired on October 1, 2020

During the period from January 1, 2018 to September 30, 2018, OMIDRIA was not reimbursed separately when used for procedures involving patients covered by Medicare Part B, and our revenues decreased significantly. After reinstatement of separate reimbursement for OMIDRIA in the fourth quarter of 2018, our revenues quickly returned to levels during which separate reimbursement was available and subsequent quarter-over-quarter revenue growth approximated historical rates. Due to the postponement of elective surgical procedures, including cataract surgery, we did not make any sales of OMIDRIA to our wholesalers from March 25 to May 19, 2020. However, by the end of June 2020, the run rate of weekly OMIDRIA sales approximated those seen prior to the pandemic.

In its 2021 OPSS proposed rule, CMS confirmed the October 1, 2020 expiration of pass-through reimbursement for OMIDRIA and consequently, pass-through reimbursement for OMIDRIA under Medicare Part B ended on October 1, 2020 and our net revenues for September were significantly reduced. CMS is expected to publish the final 2021 OPSS

rule later in 2020. However, we can provide no guarantee that CMS' final 2021 OPPS rule will provide separate reimbursement for OMIDRIA.

In 2019 CMS codified revisions to the ASC payment system pursuant to its policy to “unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting.” CMS continued this policy, without change, in 2020 and has proposed to extend it again in 2021. During the time that these revisions to the ASC payment system have been in force, they have not applied to OMIDRIA because OMIDRIA had pass-through status and, accordingly, has not been packaged. OMIDRIA does not contain an opioid, has an FDA-approved label indication for pain reduction and CMS considers it to function as a surgical supply. Because OMIDRIA is subject to packaged payment following expiration of its pass-through status, we believe that OMIDRIA now satisfies these criteria for separate payment when provided in the ASC setting. In September 2020, we submitted to CMS a comment letter on the 2021 OPPS proposed rule and a legal memorandum outlining our position that OMIDRIA meets all of the regulatory criteria established by CMS for separate payment in the ASC setting and by law should be separately paid when used in the ASC in the fourth quarter of 2020 and throughout calendar year 2021. We are also continuing to pursue other administrative and legislative avenues to secure separate payment for OMIDRIA for the remainder of 2020 and beyond. If these efforts are not successful, we expect to implement an alternative market approach, however we are likely to have significantly reduced sales of OMIDRIA until we are able to implement such strategy. We may face difficulties or delays in implementing such a strategy and, even if successfully implemented, we cannot predict whether, or to what extent, our customers would maintain or increase their utilization of OMIDRIA. See “Commercial Product - OMIDRIA” earlier in this section for additional details regarding the separate payment status for OMIDRIA.

The uncertainty around pass-through reimbursement or other separate payment status for OMIDRIA and COVID-19 will likely have a continuing adverse impact on our business, operations and financial results, limiting the number of cataract procedures which may be performed and significantly reducing demand for our commercial drug product, OMIDRIA. COVID-19 and the corresponding governmental response has and may continue to lead to disruptions in commercial sales activities, delays in our clinical trials or in the submission or review of regulatory applications. Due to the ongoing impact of the global pandemic on OMIDRIA sales, as well as the uncertain reimbursement status for OMIDRIA for the remainder of 2020 and beyond, we are unable to predict future OMIDRIA product sales, net.

Results of Operations

Revenue

Our revenue consists of OMIDRIA product sales to ASCs and hospitals in the U.S. Our product sales, net are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(In thousands)			
Product sales, net	\$ 26,114	\$ 29,856	\$ 63,181	\$ 78,389

During the three and nine months ended September 30, 2020, OMIDRIA revenue was \$26.1 million and \$63.2 million as compared to \$29.9 million and \$78.4 million for the three and nine months ended September 30, 2019. The decrease in revenue during the three months ended September 30, 2020 compared to the same period in the prior year was due to recording an \$8.7 million deduction for product returns from wholesalers, ASCs and hospitals related to the expiration of pass-through reimbursement for OMIDRIA on October 1, 2020. The additional decrease in revenue during the nine months ended September 30, 2020 compared to the same period in the prior year was due to COVID-19 related closings of ASCs and hospitals to elective cataract procedures from mid-March 2020 through to late June 2020. By the end of June 2020, the weekly run rate of OMIDRIA sales had returned to levels approaching those seen prior to the pandemic and continued to increase during the third quarter prior to recording the OMIDRIA return reserve. Given the uncertainty and local variances in the severity and response to the COVID-19 pandemic across the U.S., and whether OMIDRIA will receive separate payment, we are not able to predict future OMIDRIA revenue.

Gross-to-Net Deductions

We record OMIDRIA product sales net of estimated chargebacks, rebates, distribution fees and product returns. These deductions are generally referred to as gross-to-net deductions. Our total gross-to-net provision for the three and nine months ended September 30, 2020 was 46.8% and 36.6% of gross OMIDRIA product sales, respectively. This compares to 28.5% and 28.0% for the three and nine months ended September 30, 2019, respectively. The increase in gross-to-net deductions as a percentage of sales in 2020 compared to 2019 is due to the OMIDRIA return provision recorded in the third quarter of 2020.

A summary of our gross-to-net related accruals for the nine months ended September 30, 2020 is as follows:

	<u>Chargebacks and Rebates</u>	<u>Distribution Fees and Product Return Allowances</u> (In thousands)	<u>Total</u>
Balance as of December 31, 2019	\$ 10,240	\$ 2,237	\$ 12,477
Provisions	20,345	16,179	36,524
Payments	(25,793)	(4,205)	(29,998)
Balance as of September 30, 2020	<u>\$ 4,792</u>	<u>\$ 14,211</u>	<u>\$ 19,003</u>

Chargebacks and Rebates

We record a provision for estimated chargebacks and rebates at the time we recognize OMIDRIA product sales revenue and reduce the accrual when payments are made or credits are granted. Our chargebacks are related to a pharmaceutical pricing agreement, a federal supply schedule agreement, a 340B prime vendor agreement, a Medicaid drug rebate agreement and an off-invoice discount to our ASC and hospital customers. We also record a provision for our OMIDRIAssure[®] patient assistance and reimbursement services program and our rebates under our purchase volume-discount programs.

Distribution Fees and Product Return Allowances

We pay our wholesalers a distribution fee for services they perform for us based on the dollar value of their purchases of OMIDRIA. We record a provision for these charges as a reduction to revenue at the time of sale to the wholesaler and make payments to our wholesalers based on contractual terms.

We allow for the return of product up to 12 months past its expiration date, or for product that is damaged or not used by our customers. We record a provision for returns upon sale of OMIDRIA to our wholesaler. When a return or claim is received, we issue a credit memo to the wholesaler against its outstanding receivable to us or we reimburse the customer. During the three months ended September 30, 2020 we estimated and recorded an \$8.7 million provision for potential returns from our wholesalers, ASCs and hospital customers due to the October 1, 2020 expiration of pass-through reimbursement for OMIDRIA.

Research and Development Expenses

Our research and development expenses can be divided into three categories: direct external expenses, which include clinical research and development, preclinical research and development activities; internal, overhead and other expenses; and stock-based compensation expense. Direct external expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations prior to receiving regulatory approval for a product candidate, contract research organizations, clinical trial sites, collaborators, consultants, and licensors consultants. Costs are reported in preclinical research and development until the program enters the clinic. Internal, overhead and other expenses consist of personnel costs, overhead costs such as rent, utilities and depreciation and other miscellaneous costs. We do not generally allocate our internal resources, employees and infrastructure to any individual research project because we deploy them across multiple clinical and preclinical projects that we are advancing in parallel.

The following table illustrates our expenses associated with these activities:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(In thousands)			
Direct external expenses:				
Clinical research and development:				
MASP-2 program - OMS721 (narsoplimab)	\$ 10,624	\$ 9,120	\$ 33,559	\$ 28,615
MASP-3 program - OMS906	6,172	—	6,172	—
OMIDRIA - Ophthalmology	206	657	1,090	1,744
PDE7 - OMS527	134	1,425	1,730	3,019
Total clinical research and development	17,136	11,202	42,551	33,378
Preclinical research and development	2,012	3,625	8,846	6,827
Total direct external expenses	19,148	14,827	51,397	40,205
Internal, overhead and other expenses	10,532	7,361	28,248	24,205
Stock-based compensation expense	1,636	1,558	4,714	4,698
Total research and development expenses	\$ 31,316	\$ 23,746	\$ 84,359	\$ 69,108

Total direct research and development expenses increased \$4.3 million and \$11.2 million, respectively, for the three and nine months ended September 30, 2020 compared to the same periods in 2019. The \$4.3 million increase for the three months ended September 30, 2020 is due to a \$5.0 million access fee payable upon entry into a newly signed technology license agreement with a third party related to the MASP-3 program, which began clinical trials in the third quarter of 2020. The \$11.2 million increase for the nine months ended September 30, 2020 is primarily due to the \$5.0 million access fee payable under the technology license agreement related to the MASP-3 program entered into during the third quarter of 2020, increased IgA nephropathy clinical trial costs, and additional HSCT-TMA costs related to the preparation of our rolling BLA and disease awareness activities.

We expect the majority of our research and development expenses for the remainder of 2020 to be related to our narsoplimab and MASP-3 programs. We expect overall research and development costs in the fourth quarter 2020 to increase slightly from current levels as we manufacture additional drug substance and expand our disease awareness activities in preparation for the anticipated U.S. commercial launch of narsoplimab in HSCT-TMA. These increases will be partially offset by the absence of technology license agreement costs in the fourth quarter of 2020.

At this time, we are unable to estimate with certainty the longer-term costs we will incur in the continued development of our product candidates due to the inherently unpredictable nature of our preclinical and clinical development activities, as well as the potential impacts of the COVID-19 pandemic. Clinical development timelines, the probability of success and development costs can differ materially as new data become available and as expectations change. Our future research and development expenses will depend, in part, on the preclinical or clinical success of each product candidate as well as ongoing assessments of each program's commercial potential. In addition, we cannot forecast with precision which product candidates, if any, may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

We are required to expend substantial resources in the development of our product candidates due to the lengthy process of completing clinical trials and seeking regulatory approval. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could delay our generation of product revenue and increase our research and development expenses.

Selling, General and Administrative Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(In thousands)			
Selling, general and administrative expenses, excluding stock-based compensation expense	\$ 17,637	\$ 14,995	\$ 48,384	\$ 42,723
Stock-based compensation expense	2,188	1,938	6,408	5,770
Total selling, general and administrative expenses	\$ 19,825	\$ 16,933	\$ 54,792	\$ 48,493

Total selling, general and administrative expenses increased \$2.9 million and \$6.3 million, respectively, for the three and nine months ended September 30, 2020. The increase in selling, general and administrative expenses during the three and nine months ended September 30, 2020 compared to the same periods in 2019 was primarily due to increased pre-commercialization activities for narsoplimab, including costs related to product training.

We expect that our selling, general and administrative expenses will increase during the fourth quarter of 2020 compared to current levels, primarily due to increased pre-commercialization activities for narsoplimab.

Interest Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(In thousands)			
Interest expense	\$ 6,882	\$ 5,715	\$ 18,763	\$ 16,846

Interest expense is comprised of contractual interest and amortization of debt issuance and debt discount related to our 2023 and 2026 Notes, as well as interest on our finance leases. We expect that our fourth quarter 2020 interest expense will be approximately \$8.0 million. For more information, see “Note 6—Unsecured Convertible Senior Notes.”

Loss on Early Extinguishment of Debt

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(In thousands)			
Loss on early extinguishment of debt	\$ 13,374	\$ —	\$ 13,374	\$ —

In August 2020, we issued the 2026 Notes and repurchased \$115.0 million of the previously outstanding 2023 Notes. We recorded a \$13.4 million loss on early extinguishment of debt related to the unamortized discount and issuance costs related to the repurchased 2023 Notes in the three and nine months ended September 30, 2020.

Income Tax Benefit

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(In thousands)			
Income tax benefit	\$ 7,854	\$ —	\$ 7,854	\$ —

During the third quarter of 2020, we issued the 2026 Notes which created an income tax benefit of \$7.9 million. We anticipate that we will recognize an additional income tax benefit of \$4.1 million during the fourth quarter of 2020. See “Note 6—Unsecured Convertible Senior Notes.”

Financial Condition - Liquidity and Capital Resources

As of September 30, 2020, we had \$153.5 million in cash, cash equivalents and short-term investments available for general corporate use held primarily in money-market accounts. In addition, as of September 30, 2020, we had \$37.4 million in accounts receivable, net. We have historically generated net losses and incurred negative cash flows from operations and debt service. For the nine months ended September 30, 2020, we incurred net losses of \$100.8 million and incurred negative cash flows from operations of \$81.7 million. We expect to continue to incur losses from operations until our revenues exceed operating costs and debt service obligations.

OMIDRIA pass-through reimbursement from CMS expired on October 1, 2020. If continued separate payment is determined not to be reasonably achievable in the near term, we have developed a commercial strategy that can be quickly implemented to lower the per-vial sales price of OMIDRIA to achieve substantially larger sales volumes. We believe that this approach would result in substantial revenues from OMIDRIA, in part because CMS Medicare Part B beneficiaries only represent approximately 45% of cataract surgery procedures annually.

We anticipate narsoplimab for HSCT-TMA will receive FDA approval and will launch in early to mid-2021. Currently we cannot fully predict the timing or the magnitude of narsoplimab revenues, but we believe they will be significant. Execution of our sales and marketing strategies for the launch of narsoplimab for HSCT-TMA is underway. These plans include various milestones at which we commit to incremental activities, providing for flexibility in the timing of costs incurred should the approval of narsoplimab be accelerated or delayed. If warranted, we will adjust the timing and associated costs of our HSCT-TMA launch activities as we advance through the BLA review and approval process.

We plan to continue to fund our operations for at least the next twelve months with our cash and investments on hand, from sales of OMIDRIA and, if FDA approval is granted, from sales of narsoplimab for HSCT-TMA. There is also that possibility that narsoplimab will generate revenues in the treatment of COVID-19. In addition, we may utilize funds available under our accounts receivable-based line of credit, which allows us to borrow up to 85% of our available accounts receivable borrowing base, less certain reserves, or \$50.0 million, whichever is less. Should it be necessary or determined to be strategically advantageous, we also could pursue debt financings, public and private offerings of our equity securities similar to those we have completed previously, or other strategic transactions, which may include licensing a portion of our existing technology. Should it be necessary to manage our operating expenses, we would reduce our projected cash requirements through reduction of our expenses by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

Cash Flow Data

	Nine Months Ended September 30,	
	2020	2019
(In thousands)		
Selected cash flow data		
Cash provided by (used in):		
Operating activities	\$ (81,679)	\$ (37,059)
Investing activities	\$ (75,027)	\$ 35,838
Financing activities	\$ 174,697	\$ 4,221

Operating Activities. Net cash used in operating activities for the nine months ended September 30, 2020 increased by \$44.6 million as compared to the same period in 2019. The net increase is primarily due to an increase in our net loss of \$45.5 million, which was partially offset by an increase in non-cash charges of \$8.3 million. In addition, cash used in accounts payable and accrued expense increased by \$15.6 million. These increases were partially offset by a \$4.9 million increase in cash provided from collections of accounts receivable.

Investing Activities. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and proceeds from the sale of short-term investments, thus causing a shift between our cash and cash equivalents and short-term investment balances. Because we manage our cash usage with respect to our total cash, cash

equivalents and short-term investments, we do not consider fluctuations in cash flows from investing activities to be important to the understanding of our liquidity and capital resources.

Net cash used in investing activities during the nine months ended September 30, 2020 was \$75.0 million, a decrease of \$110.9 million for the same period in 2019 driven by an increase in purchases of investments of \$132.6 million offset by proceeds from sale and maturities of investments of \$21.7 million.

Financing Activities. Net cash provided by financing activities during the nine months ended September 30, 2020 was \$174.7 million, an increase of \$170.5 million compared to the same period in 2019. The increase for the nine months ended September 30, 2020 compared to the prior year was due to receiving cash proceeds of \$218.2 million from the issuance of our 2026 Notes and \$7.5 million from the termination of the 2023 Capped Call contract offset by \$125.6 million to repurchase our 2023 Notes and \$23.2 million to purchase the 2026 Capped Call. In addition, we received net proceeds of \$93.7 million from our August 2020 public offering of our common stock.

Line of Credit Agreement. Our Line of Credit Agreement with Silicon Valley Bank provides for a \$50.0 million revolving line of credit facility. Under the Line of Credit Agreement we may draw, on a revolving basis, up to the lesser of \$50.0 million or 85.0% of our eligible accounts receivable, less certain reserves. The Line of Credit Agreement is secured by all our assets excluding intellectual property and development program inventories and matures on August 2, 2022. As of September 30, 2020, we had no outstanding borrowings under the Line of Credit Agreement, and we were in compliance with all covenants in all material respects. See earlier discussion under “Liquidity and Capital Resources” for further detail regarding the availability of the line of credit.

Contractual Obligations and Commitments

The following table presents a summary of our contractual obligations and commitments as of September 30, 2020.

	Payments Due Within				Total
	1 Year	2-3 Years	4-5 Years	More than 5 Years	
	(In thousands)				
Operating leases	\$ 1,616	\$ 13,214	\$ 13,795	\$ 19,590	\$ 48,215
Finance leases (principal and interest)	364	1,809	198	—	2,371
Unsecured convertible senior notes	4,438	35,503	123,823	238,321	402,085
Goods & services	14,835	10,179	10,854	—	35,868
Total	<u>\$ 21,253</u>	<u>\$ 60,706</u>	<u>\$ 148,670</u>	<u>\$ 257,911</u>	<u>\$ 488,539</u>

Lease Agreements

We lease our office and laboratory space in The Omeros Building under a lease agreement with BMR - 201 Elliott Avenue LLC. The initial term of the lease ends in November 2027, and we have two options to extend the lease term, each by five years. As of September 30, 2020, the remaining aggregate non-cancelable rent payable under the initial term of the lease, excluding common area maintenance and related operating expenses, is \$48.2 million.

Unsecured Convertible Senior Notes

For more information, see “Note 6—Unsecured Convertible Senior Notes.”

Goods and Services

We have certain other non-cancelable obligations under various agreements that relate to goods and services. As of September 30, 2020, our aggregate firm commitments were \$35.9 million.

We may be required, in connection with in-licensing or asset acquisition agreements, to make certain royalty and milestone payments and we cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. Therefore, such payments are not included in the amount above.

Critical Accounting Policies and Significant Judgments and Estimates

There have not been any material changes in our critical accounting policies and significant judgments and estimates as disclosed in Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2019.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is primarily confined to our investment securities. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities. As of September 30, 2020, we had cash, cash equivalents and short-term investments of \$153.5 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These securities in our investment portfolio are not leveraged and are classified as available-for-sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates and, with our current portfolio of short-term investments, we are not exposed to potential loss due to changes in interest rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2020. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2020, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, in the ordinary course of business, we may be involved in various claims, lawsuits and other proceedings. As of the date of filing of this Quarterly Report on Form 10-Q, we were not involved in any material legal proceedings.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of risks and uncertainties. Before making an investment decision you should carefully consider the risks described in Part I, Item 1A, “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on March 2, 2020. In assessing the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2019, you should also refer to the other information included therein and in this Quarterly Report on Form 10-Q. In addition, we may be adversely affected by risks that we currently deem immaterial or by other risks that are not currently known to us. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment.

The risk factors set forth below update, and should be read together with, the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2019.

Our ability to continue as a going concern and achieve profitability is highly dependent on the commercial success of OMIDRIA, and to the extent OMIDRIA is not successful, our business, financial condition and results of operations would be materially adversely affected, and the price of our common stock may decline.

OMIDRIA is currently our only product that has been approved by the FDA for commercial sale in the U.S. For the three months ended September 30, 2020, we recorded net sales of OMIDRIA of \$26.1 million. Revenues from sales of OMIDRIA have not been sufficient to fund our operations fully in prior periods and we cannot provide assurance that revenues from OMIDRIA sales will be sufficient to fund our operations fully in the future. In prior periods, when OMIDRIA was not reimbursed separately under Medicare Part B, our revenues decreased significantly. In the absence of other revenue sources, we will need to generate substantially more product revenue from OMIDRIA to achieve and sustain profitability. We may be unable to sustain or increase revenues generated from OMIDRIA product sales for a number of reasons, including:

- the significant reduction in the volume of ophthalmic surgical procedures and corresponding reduction in demand for OMIDRIA as a result of the COVID-19 pandemic;
- the expiration of pass-through reimbursement on October 1, 2020 and uncertainty regarding the extent of coverage and reimbursement for OMIDRIA when used in Medicare patients;
- pricing, coverage and reimbursement policies of government and private payers such as Medicare, Medicaid, the U.S. Department of Veterans Affairs, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- a lack of acceptance by physicians, patients and other members of the healthcare community;
- the availability, relative price and efficacy of the product as compared to alternative treatment options or branded, compounded or generic competing products;
- an unknown safety risk;
- the failure to enter into and maintain acceptable partnering arrangements for marketing and distribution of OMIDRIA outside of the U.S.; and

- changed or increased regulatory restrictions in the U.S., EU or other foreign territories.

Pass-through reimbursement for OMIDRIA under Medicare Part B expired on October 1, 2020. In the event that we are not able to secure separate payment or similar reimbursement for OMIDRIA, or if there is a delay in securing separate payment or similar reimbursement for OMIDRIA, our revenue from OMIDRIA could decrease significantly as was the case during the period from January 1, 2018 to September 30, 2018, when OMIDRIA was not reimbursed separately when used for procedures involving patients covered by Medicare Part B.

Any decline in sales from OMIDRIA also would impact our ability to borrow under the Loan Agreement since the amount we can borrow is dependent on our eligible receivables.

If legislative and/or administrative means to secure separate payment for OMIDRIA are not successful, we would need to pursue an alternative sales strategy, and our revenues and financial condition could be adversely and significantly affected.

Pass-through reimbursement status allows for separate payment (i.e., outside the packaged payment rate for the surgical procedure) under Medicare Part B. In March 2018, Congress extended pass-through reimbursement status for a small number of drugs, including OMIDRIA, used during procedures performed on Medicare Part B fee-for-service patients through September 30, 2020. In its 2021 OPSS final rule, CMS confirmed the October 1, 2020 expiration of pass-through reimbursement for OMIDRIA and indicated an intention to package payment for OMIDRIA within the ambulatory payment classification for the associated surgical procedure in both the hospital outpatient department and ASC settings. We are continuing to pursue separate payment for OMIDRIA and have submitted to CMS a comment letter and a legal memorandum outlining our position that OMIDRIA meets all of the regulatory criteria established by CMS for separate payment in the ASC setting. However, we can provide no assurances that separate reimbursement for OMIDRIA will be available for the remainder of 2020 and beyond or, if available, that the reimbursement rate will be adequate. If the future reimbursement status of OMIDRIA continues to be uncertain, then demand for OMIDRIA from ASCs and hospitals may be reduced substantially. In such event, sales to our wholesalers may decrease correspondingly, as they adjust on-hand inventory in anticipation of reduced demand from end users.

If we are unable to obtain separate payment for OMIDRIA, we expect to pursue an alternative sales strategy. We may face difficulties or delays in implementing an alternative sales strategy and, even if successfully implemented, we cannot predict how quickly, or if, our customers would increase their OMIDRIA utilization, and the net revenues we receive from sales of OMIDRIA could be reduced, potentially by a significant amount. Additionally, private payers often follow CMS with respect to reimbursement for new drugs, and they may cease or decrease coverage or reimbursement for OMIDRIA if we are unable to obtain separate payment for OMIDRIA from CMS. A reduction in OMIDRIA revenues for these or any other reasons may also impair our ability to borrow under our line of credit facility with Silicon Valley Bank.

Any of these risks, if realized, would adversely affect our ability to generate revenue and attain profitability, and there would be a material adverse effect on our business, financial condition, results of operations and growth prospects and the trading price of our stock could decline.

The spread of COVID-19 and efforts to reduce its transmission may negatively impact our business, operations and financial results.

The COVID-19 pandemic has significantly affected the global economy and has adversely affected our sales of OMIDRIA due to a reduction in the overall volume of cataract surgery and intraocular lens replacement procedures. In March 2020, ASCs and hospitals using OMIDRIA postponed nearly all cataract procedures in response to recommendations from government and medical organizations. As a result, we did not record any sales of OMIDRIA to our wholesalers from March 25 to May 19, 2020. Beginning in the second half of May 2020, cataract surgeries resumed to varying degrees in locations throughout the country. If the number of cataract procedures becomes or continues to be limited, either by necessity for time-consuming safety protocols, reduction in patient demand, or the imposition of prohibitions on elective surgeries in some localities, then we would expect there to be a corresponding reduction in demand for OMIDRIA.

We may also experience disruptions to our operations due to COVID-19, such as delays or disruptions with respect to manufacturing of clinical or commercial drug substance or drug product and delays in our clinical trials or in the submission or review of regulatory applications. Such delays or disruptions could negatively affect our commercial

operations, clinical programs, and research and development. The health of our employees, contractors and other persons on whom we rely may be adversely affected by COVID-19. Although we are taking precautionary measures intended to help minimize the risk of the virus to our employees, these measures may be ineffective or may otherwise adversely affect our productivity. In addition, the conditions created by the pandemic may intensify other risks inherent in our business. Due to the unknown magnitude, duration and outcome of the COVID-19 pandemic, it is not possible to estimate precisely its impact on our business, operations or financial results; however, the impact could be material.

To the extent COVID-19 adversely affects our business, financial condition, and results of operations and global economic conditions more generally, it may also have the effect of heightening many of the other risk factors set forth herein as well as those described in “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2019.

We may be unable to further evaluate narsoplimab in COVID-19 patients and there can be no guarantee that the results of any such evaluations will be favorable.

In response to the COVID-19 pandemic, we initiated a compassionate use program for narsoplimab to treat COVID-19 patients with ARDS. While all six COVID-19 patients initially treated with narsoplimab survived, recovered, and were discharged from the hospital, and we believe the results observed following narsoplimab treatment in severe COVID-19 cases demonstrate the similarity in pathophysiology between COVID-19 and HSCT-TMA, we cannot provide assurance that the results observed in the compassionate use program will be observed in any future study of narsoplimab for this indication or that we will receive regulatory authorization or approval for narsoplimab in the treatment of hospitalized patients with COVID-19. We may be unable to design and conduct a large-scale clinical trial evaluating narsoplimab in COVID-19, secure the large-scale manufacturing capacity from third parties necessary to manufacture narsoplimab in sufficient quantities to enable broader availability of narsoplimab for COVID-19 patients, or secure funding and other resources necessary for us to conduct these activities from government or other sources. In addition, another party may be successful in producing a vaccine or an alternative therapy for COVID-19 or ARDS associated with COVID-19, which may also lead to the diversion of governmental and other potential sources of funding away from us and toward other companies and limit the viability of any approved or authorized product candidate for the treatment of COVID-19. Any therapeutic candidate that we may develop to address COVID-19 will be subject to risks in addition to those normally associated with pharmaceutical research, development, and commercialization, such as higher risk of technical failure, lower and transient opportunities for revenue, higher manufacturing costs, product safety or efficacy risks related to an expedited research and development timeline, and novel liability theories. Relatedly, FDA may require that we conduct a large-scale trial of narsoplimab in COVID-19 patients in order to grant any approval or authorization. These risks may affect our ability to develop or commercialize a therapeutic for COVID-19 or any other current or future indication.

If our clinical trials or clinical protocols are delayed, suspended or terminated, we may be unable to develop our product candidates on a timely basis, which would adversely affect our ability to obtain regulatory approvals, increase our development costs and delay or prevent commercialization of approved products.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials or clinical data collection protocols that will cause regulatory agencies, institutional review boards or ethics committees, or us to delay our clinical trials or suspend or delay the analysis of the data from those trials. Clinical trials and clinical data protocols can be delayed for a variety of reasons, including:

- discussions with the FDA, the EMA or other foreign authorities regarding the scope or design of our clinical trials or clinical data collection protocols;
- delays or the inability to obtain required approvals from institutional review boards, ethics committees or other responsible entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials, collecting data from enrolled patients, adequately monitoring patients before or after treatment, or collecting historical control data for any reason including disease severity, trial or data collection protocol design, study eligibility criteria, patient population size (e.g., for orphan diseases or for some pediatric indications), proximity or availability of clinical trial sites for prospective patients, availability of competing therapies and clinical trials, regional differences in diagnosis and treatment, perceived

risks and benefits of the product or product candidate, physician patient referral practices, disruptions due to external events, including an outbreak of pandemic or contagious disease such as the COVID-19 coronavirus, which has slowed enrollment in our clinical trials of narsoplimab in patients with IgA nephropathy;

- lower than anticipated retention rates of patients in clinical trials;
- the need to repeat or conduct additional clinical trials as a result of inconclusive or negative results, failure to replicate positive early clinical data in subsequent clinical trials, failure to deliver an efficacious dose of a product candidate, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol, an unacceptable study design or other problems;
- adverse findings in clinical or nonclinical studies related to the safety of our product candidates in humans;
- an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval;
- an unfavorable inspection or review by the FDA or other regulatory authority of a clinical trial site or records of any clinical investigation;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials;
- the suspension by a regulatory agency of a trial by imposing a clinical hold; or
- the amendment of clinical trial or data collection protocols to reflect changes in regulatory requirements and guidance or other reasons as well as subsequent re-examination of amendments to clinical trial or data collection protocols by institutional review boards or ethics committees.
- In addition, our clinical trial or development programs have been, and in the future may be, suspended or terminated by us, the FDA or other regulatory authorities, or institutional review boards or ethics committees due to a number of factors, including:
- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- the failure to remove a clinical hold in a timely manner, if at all;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks;
- inability to deliver an efficacious dose of a product candidate; or
- lack of adequate funding to continue the clinical trial or development program, including as a result of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies or increased expenses associated with the services of our contract research organizations, or other third parties.

If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to file for regulatory approval or conduct additional clinical trials on the schedule we currently anticipate. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays in completing our clinical trials could increase our development costs, could slow down our product development and

regulatory submission process, could delay our receipt of product revenue and could make it difficult to raise additional capital. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products, potentially harming our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
4.1	Indenture, dated as of August 14, 2020, between Omeros Corporation and Wells Fargo Bank, National Association, as trustee. (Incorporated by reference to Exhibit 4.1 from the Company's Current Report on Form 8-K filed on August 14, 2020)
4.2	First Supplemental Indenture, dated as of August 14, 2020, between Omeros Corporation and Wells Fargo Bank, National Association, as trustee. (Incorporated by reference to Exhibit 4.1 from the Company's Current Report on Form 8-K filed on August 14, 2020)
4.3	Form of 5.25% Convertible Senior Note due 2026 (included in Exhibit 4.2)
10.1	Tenth Amendment to Lease Agreement, dated September 15, 2020, by and between Omeros Corporation and BMR-201 Elliott Avenue LLC
10.2	Form of Capped Call Confirmation (Incorporated by reference to Exhibit 10.1 from the Company's Current Report on Form 8-K filed on August 14, 2020)
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of 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 Rule 13-14(a) or Rule 15d-14(a) of 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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Link base Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104.1	Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101)

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 SEC and are not to be incorporated by reference into any filing of Omeros Corporation under the Securities Act or the Exchange Act, 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.

OMEROS CORPORATION

Dated: November 9, 2020

/s/ Gregory A. Demopoulos
Gregory A. Demopoulos, M.D.
President, Chief Executive Officer and Chairman of the
Board of Directors

Dated: November 9, 2020

/s/ Michael A. Jacobsen
Michael A. Jacobsen
Vice President, Finance, Chief Accounting Officer and
Treasurer

TENTH AMENDMENT TO LEASE

THIS TENTH AMENDMENT TO LEASE (this "Amendment") is entered into as of this 15th day of September, 2020 (the "Tenth Amendment Execution Date"), by and between BMR-201 ELLIOTT AVENUE LLC, a Delaware limited liability company ("Landlord"), and OMEROS CORPORATION, a Washington corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant are parties to that certain Lease dated as of January 27, 2012 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of November 5, 2012, that certain Second Amendment to Lease dated as of November 16, 2012 (the "Second Amendment"), that certain Third Amendment to Lease dated as of October 16, 2013, that certain Fourth Amendment to Lease dated as of September 8, 2015, that certain Fifth Amendment to Lease dated as of September 1, 2016, that certain Sixth Amendment to Lease dated as of October 18, 2018, that certain Seventh Amendment to Lease dated as of April 15, 2019, that certain Eighth Amendment to Lease dated as of October 28, 2019 and that certain Ninth Amendment to Lease dated as of January 15, 2020 (collectively, and as the same may have been further amended, amended and restated, supplemented or modified from time to time, the "Existing Lease"), whereby Tenant leases certain premises (the "Existing Premises") from Landlord at 201 Elliott Avenue West in Seattle, Washington (the "Building"), including certain space within the Building's vivarium (such portion of the Building's vivarium currently leased to Tenant, the "Tenant's Existing Vivarium Space"), which excludes the Additional Vivarium Premises comprising approximately 5,177 square feet of Rentable Area that Tenant leased from Landlord pursuant to the Second Amendment, with respect to which Tenant exercised its right to terminate pursuant to that certain letter dated December 17, 2015 from Tenant to Landlord;

B. WHEREAS, Tenant desires to lease additional premises from Landlord in the Building's vivarium; and

C. WHEREAS, Landlord and Tenant desire to modify and amend the Existing Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Definitions. For purposes of this Amendment, capitalized terms shall have the meanings ascribed to them in the Existing Lease unless otherwise defined herein. The Existing Lease, as amended by this Amendment, is referred to collectively herein as the "Lease." From and after the date hereof, the term "Lease," as used in the Existing Lease, shall mean the Existing Lease, as amended by this Amendment.

2. Seventh Additional Vivarium Premises. Effective as of the Tenth Amendment Execution Date, Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, approximately one thousand two hundred sixty-two (1,262) aggregate additional square feet of

Rentable Area located collectively in Room 141 (consisting of approximately five hundred ninety-two (592) square feet of Rentable Area) and Room 152 (consisting of approximately six hundred seventy (670) square feet of Rentable Area) of the Vivarium, as shown on Exhibit A attached hereto (collectively, the “Seventh Additional Vivarium Premises”), for use by Tenant in accordance with the Permitted Use and in accordance with all other terms and conditions of the Lease. From and after the Tenth Amendment Execution Date, the term “Premises,” as used in the Lease shall mean the Existing Premises plus the Seventh Additional Vivarium Premises, and the term “Tenant’s Vivarium Space,” as used in the Lease, shall mean the Tenant’s Existing Vivarium Space plus the Seventh Additional Vivarium Premises.

3. Seventh Additional Vivarium Term. The Term of the Lease with respect to the Seventh Additional Vivarium Premises (as the same may be earlier terminated in accordance with the Lease, the “Seventh Additional Vivarium Term”) shall commence on the Tenth Amendment Execution Date and shall expire on the Term Expiration Date. Failure by Tenant to obtain validation by any medical review board or other similar governmental licensing of the Seventh Additional Vivarium Premises required for the Permitted Use by Tenant shall not serve to extend the commencement of the Seventh Additional Vivarium Term.

4. Condition of Seventh Additional Vivarium Premises. Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the Seventh Additional Vivarium Premises or with respect to the suitability of the Seventh Additional Vivarium Premises for the conduct of Tenant’s business. Tenant acknowledges that (a) it is fully familiar with the condition of the Seventh Additional Vivarium Premises and agrees to take the same in its condition “as is” as of the Tenth Amendment Execution Date and (b) Landlord shall have no obligation to alter, repair or otherwise prepare the Seventh Additional Vivarium Premises for Tenant’s occupancy or to pay for or construct any improvements to the Seventh Additional Vivarium Premises. Tenant’s taking of possession of the Seventh Additional Vivarium Premises shall, except as otherwise agreed to in writing by Landlord and Tenant, conclusively establish that the Seventh Additional Vivarium Premises were at such time in good, sanitary and satisfactory condition and repair.

5. Base Rent and Additional Rent. In addition to all Base Rent for the Existing Premises, commencing on the Tenth Amendment Execution Date and continuing for the duration of the Seventh Additional Vivarium Term, Tenant shall pay to Landlord (in accordance with the provisions of the Lease) Base Rent for the Seventh Additional Vivarium Premises. Base Rent (including the monthly installments of Base Rent) for the Seventh Additional Vivarium Premises shall equal the applicable amounts set forth on Exhibit B attached hereto. In addition to all Additional Rent for the Existing Premises, commencing as of the Tenth Amendment Execution Date and continuing for the duration of the Seventh Additional Vivarium Term, Tenant shall pay to Landlord Additional Rent (as defined in (and in accordance with the provisions of) the Lease) with respect to the Seventh Additional Vivarium Premises.

6. Pro Rata Share. Tenant’s Pro Rata Share of the Project with respect to the Seventh Additional Vivarium Premises shall be 0.83%. Therefore, commencing as of the Tenth Amendment Execution Date, Tenant’s Pro Rata Share of the Project for the entire Premises (i.e., the Existing Premises plus the Seventh Additional Vivarium Premises) shall be 74.44%.

7. Termination Option. Notwithstanding anything to the contrary in the Lease, Tenant shall have the right to terminate the Lease, but only with respect to the Seventh Additional Vivarium Premises (and no less than all of the Seventh Additional Vivarium Premises), by providing written notice (the "Seventh Additional Vivarium Termination Notice") to Landlord at least sixty (60) days prior to Tenant's desired termination date (the "Seventh Additional Vivarium Termination Date"), which Seventh Additional Vivarium Termination Date shall be set forth in the Seventh Additional Vivarium Termination Notice. Subject to (a) Landlord's timely receipt of the Seventh Additional Vivarium Termination Notice and (b) Tenant surrendering the Seventh Additional Vivarium Premises in the condition required under the Lease (including, without limitation, Section 18.2 and Article 26 of the Lease), then, as of the Seventh Additional Vivarium Termination Date, the Lease with respect to the Seventh Additional Vivarium Premises only shall terminate and be of no further force or effect, and Landlord and Tenant shall be relieved of their respective obligations under the Lease with respect to the Seventh Additional Vivarium Premises only from and after the Seventh Additional Vivarium Termination Date, except with respect to those obligations set forth in the Lease that expressly survive the expiration or earlier termination thereof, including payment by Tenant of all amounts owed by Tenant pursuant to the Lease with respect to the Seventh Additional Vivarium Premises for the period up to and including the Seventh Additional Vivarium Termination Date. The termination right granted to Tenant pursuant to this Section shall automatically terminate and be of no further force or effect in the event that (y) Tenant assigns, subleases or otherwise Transfers the Seventh Additional Vivarium Premises or any portion thereof to other entities or persons, other than in connection with an Exempt Transfer (or in connection with any sublease approved by Landlord pursuant to Article 29 of the Lease), or (z) Tenant's right to possession of the Seventh Additional Vivarium Premises has previously been terminated. The termination right granted to Tenant pursuant to this Section is personal to Omeros Corporation, a Washington corporation ("Omeros") and any Permitted Transferees of Omeros, and may not be exercised by any other assignee, sublessee or transferee of Tenant's or a Permitted Transferee's interest in the Lease.

8. Broker. Tenant represents and warrants that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment and agrees to reimburse, indemnify, save, defend (at Landlord's option and with counsel reasonably acceptable to Landlord, at Tenant's sole cost and expense) and hold harmless the Landlord Indemnitees for, from and against any and all cost or liability for compensation claimed by any such broker or agent employed or engaged by it or claiming to have been employed or engaged by it.

9. No Default. Tenant represents, warrants and covenants that, to the best of Tenant's knowledge, Landlord and Tenant are not in default of any of their respective obligations under the Existing Lease and no event has occurred that, with the passage of time or the giving of notice (or both) would constitute a default by either Landlord or Tenant thereunder.

10. Effect of Amendment. Except as modified by this Amendment, the Existing Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. In the event of any conflict between the terms contained in this Amendment and the Existing Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties.

11. Successors and Assigns. Each of the covenants, conditions and agreements contained in this Amendment shall inure to the benefit of and shall apply to and be binding upon the parties hereto and their respective heirs, legatees, devisees, executors, administrators and permitted successors and assigns and sublessees. Nothing in this section shall in any way alter the provisions of the Lease restricting assignment or subletting.

12. Miscellaneous. This Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Amendment are inserted and included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease, lease amendment or otherwise until execution by and delivery to both Landlord and Tenant.

13. Authority. Tenant guarantees, warrants and represents that the individual or individuals signing this Amendment have the power, authority and legal capacity to sign this Amendment on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed.

14. Counterparts; Facsimile, Electronic and PDF Signatures. This Amendment may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document. A facsimile, electronic or portable document format (PDF) signature on this Amendment shall be equivalent to, and have the same force and effect as, an original signature.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the date and year first above written.

LANDLORD:

BMR-201 ELLIOTT AVENUE LLC,
a Delaware limited liability company

By: /s/ Kevin M. Simonsen
Name: Kevin M. Simonsen
Title: EVP & General Counsel

TENANT:

OMEROS CORPORATION,
a Washington corporation

By: /s/ Michael Jacobsen
Name: Michael Jacobsen
Title: VP, Finance and Chief Accounting
Officer

EXHIBIT A

SEVENTH ADDITIONAL VIVARIUM PREMISES

EXHIBIT B

BASE RENT FOR SEVENTH ADDITIONAL VIVARIUM PREMISES

<u>Dates</u>	<u>Square Feet of Rentable Area</u>	<u>Annual Base Rent per Square Foot Of Rentable Area</u>	<u>Monthly Base Rent</u>
Tenth Amendment Execution Date - November 15, 2020	1,262	\$73.79	\$7,760.25
November 16, 2020- November 15, 2021	1,262	\$76.01	\$7,993.72
November 16, 2021- November 15, 2022	1,262	\$78.29	\$8,233.50
November 16, 2022- November 15, 2023	1,262	\$80.63	\$8,479.59
November 16, 2023- November 15, 2024	1,262	\$83.05	\$8,734.09
November 16, 2024- November 15, 2025	1,262	\$85.55	\$8,997.01
November 16, 2025- November 15, 2026	1,262	\$88.11	\$9,266.24
November 16, 2026- November 15, 2027	1,262	\$90.76	\$9,544.93

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a)/15d-14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002**

I, Gregory A. Demopoulos, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Omeros Corporation;
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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) 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.

Dated: November 9, 2020

/s/ Gregory A. Demopoulos
Gregory A. Demopoulos, M.D.
Principal Executive Officer

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE
SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002**

I, Michael A. Jacobsen, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Omeros Corporation;
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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) 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.

Dated: November 9, 2020

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer

**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**

In connection with the Quarterly Report on Form 10-Q of Omeros Corporation (the "Company") for the quarter ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Dated: November 9, 2020

/s/ Gregory A. Demopulos

Gregory A. Demopulos, M.D.
Principal Executive Officer

**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**

In connection with the Quarterly Report on Form 10-Q of Omeros Corporation (the “Company”) for the quarter ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Dated: November 9, 2020

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer
