
**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 June 30, 2020
or

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

For the transition period from _____ to _____
Commission file number: 001-34475

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 August 6, 2020, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 54,518,358.

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 permanent separate or similar reimbursement for OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% from the Centers for Medicare & Medicaid Services (CMS) for periods after September 30, 2020, 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;
 - 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, and expectations for the treatment of additional COVID-19 patients in clinical trials or other settings;
 - with respect to our narsoplimab clinical programs, our expectations regarding: whether enrollment in any or all ongoing and planned Phase 3 and Phase 2 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;
 - 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);
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- 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 JUNE 30, 2020

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

	<u>June 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,964	\$ 3,084
Short-term investments	14,124	57,704
Receivables, net	15,780	35,185
Inventory	1,892	1,147
Prepaid expense and other assets	5,167	6,625
Total current assets	38,927	103,745
Property and equipment, net	3,109	3,829
Right of use assets	26,603	27,082
Restricted investments	1,154	1,154
Advanced payments, non-current	896	1,159
Total assets	<u>\$ 70,689</u>	<u>\$ 136,969</u>
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	\$ 8,507	\$ 5,328
Accrued expenses	25,838	46,627
Current portion of lease liabilities	3,702	3,504
Total current liabilities	38,047	55,459
Lease liabilities, non-current	30,540	32,318
Unsecured convertible senior notes, net	163,372	158,213
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 June 30, 2020 and December 31, 2019.	—	—
Common stock, par value \$0.01 per share, 150,000,000 shares authorized at June 30, 2020 and December 31, 2019; 54,515,858 and 54,200,810 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively.	545	542
Additional paid-in capital	635,121	625,048
Accumulated deficit	(796,936)	(734,611)
Total shareholders' deficit	(161,270)	(109,021)
Total liabilities and shareholders' deficit	<u>\$ 70,689</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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Product sales, net	\$ 13,530	\$ 26,753	\$ 37,067	\$ 48,532
Costs and expenses:				
Cost of product sales	147	55	414	186
Research and development	24,132	19,108	53,043	45,363
Selling, general and administrative	16,931	16,928	34,967	31,560
Total costs and expenses	41,210	36,091	88,424	77,109
Loss from operations	(27,680)	(9,338)	(51,357)	(28,577)
Interest expense	(5,978)	(5,530)	(11,880)	(11,130)
Other income	364	415	912	909
Net loss	\$ (33,294)	\$ (14,453)	\$ (62,325)	\$ (38,798)
Comprehensive loss	\$ (33,294)	\$ (14,453)	\$ (62,325)	\$ (38,798)
Basic and diluted net loss per share	\$ (0.61)	\$ (0.29)	\$ (1.14)	\$ (0.79)
Weighted-average shares used to compute basic and diluted net loss per share	54,513,337	49,084,093	54,406,575	49,048,432

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Six Months Ended June 30,	
	2020	2019
Operating activities:		
Net loss	\$ (62,325)	\$ (38,798)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,298	6,973
Non-cash interest expense	5,159	4,435
Depreciation and amortization	814	827
Changes in operating assets and liabilities:		
Receivables	19,405	(5,697)
Inventory	(745)	(1,099)
Prepaid expenses and other assets	1,881	1,975
Accounts payable and accrued expenses	(18,225)	1,847
Net cash used in operating activities	<u>(46,738)</u>	<u>(29,537)</u>
Investing activities:		
Purchases of property and equipment	(210)	(279)
Purchases of investments	(3,188)	(472)
Proceeds from the sale and maturities of investments	46,768	27,250
Net cash provided by investing activities	<u>43,370</u>	<u>26,499</u>
Financing activities:		
Proceeds upon exercise of stock options	2,778	1,708
Principal payments on finance lease liabilities	(530)	(545)
Net cash provided by financing activities	<u>2,248</u>	<u>1,163</u>
Net decrease in cash and cash equivalents	(1,120)	(1,875)
Cash and cash equivalents at beginning of period	3,084	5,861
Cash and cash equivalents at end of period	<u>\$ 1,964</u>	<u>\$ 3,986</u>
Supplemental cash flow information		
Cash paid for interest	<u>\$ 6,721</u>	<u>\$ 6,731</u>
Property acquired under finance lease	<u>\$ 44</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 June 30, 2020 and December 31, 2019 and for the three and six months ended June 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 September 30, 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 other administrative and legislative avenues to secure permanent separate payment or similar reimbursement for OMIDRIA beyond September 30, 2020; however, we cannot provide assurance that these efforts will be successful.

The outbreak of the novel strain of coronavirus (SARS-CoV-2) that causes the Coronavirus Disease 2019 (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. Beginning in the second half of May 2020, cataract surgery resumed to varying degrees in locations throughout the country. 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 could be material.

Going Concern Discussion

As of June 30, 2020, we had cash, cash equivalents and short-term investments of \$16.1 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 \$51.4 million and \$63.4 million for the six months ended June 30, 2020, and the year ended December 31, 2019, respectively. Cash used in operating activities was \$46.7 million and \$60.1 million for the six months ended June 30, 2020, and the year ended December 31, 2019, respectively. We will continue to incur losses from operating activities until our revenues exceed operating costs and debt service obligations.

OMIDRIA pass-through reimbursement is scheduled to expire on September 30, 2020, and our sales of OMIDRIA continue to be affected by and are potentially at risk due to the COVID-19 pandemic. As such, we cannot predict future OMIDRIA revenues in 2020 and beyond. Similarly, we are unable to include in the determination regarding our prospects as a going concern amounts available under our accounts receivable-based line of credit or any proceeds from debt transactions or other financing instruments despite our successful track record in accessing capital through these avenues. We also have not included any potential partnerships related to our products or product candidates. Regardless of whether we secure continued pass-through payment for OMIDRIA, our working capital needs will likely continue to increase, particularly if the disruption to our operations caused by the COVID-19 pandemic continues. The conditions described above, when evaluated within the constraints of the accounting literature, raise substantial doubt with respect to our ability to meet our obligations through August 10, 2021 and, therefore, to continue as a going concern.

We plan to continue to fund our operations through proceeds from sales of OMIDRIA and, 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. If these capital sources, for any reason, are needed but inaccessible, it would have a material negative effect on our financial condition. 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.

The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.

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.

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.

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 six months ended June 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:

	June 30,	
	2020	2019
Outstanding options to purchase common stock	12,785,685	11,800,959
Outstanding warrants to purchase common stock	243,115	243,115
Total potentially dilutive shares excluded from loss per share	<u>13,028,800</u>	<u>12,044,074</u>

Note 3—Certain Balance Sheet Accounts

Accounts Receivable, net

Accounts receivable, net consist of the following:

	June 30, 2020	December 31, 2019
	(In thousands)	
Trade receivables, net	\$ 15,694	\$ 35,074
Sublease and other receivables	86	111
Total accounts receivables, net	<u>\$ 15,780</u>	<u>\$ 35,185</u>

Trade receivables are shown net of \$1.1 million and \$1.6 million of chargeback and product return allowances as of June 30, 2020 and December 31, 2019, respectively.

Inventory

Inventory consists of the following:

	June 30, 2020	December 31, 2019
	(In thousands)	
Raw materials	\$ 91	\$ 91
Work-in-progress	1,195	338
Finished goods	606	718
Total inventory	<u>\$ 1,892</u>	<u>\$ 1,147</u>

Property and Equipment, Net

Property and equipment, net consists of the following:

	June 30, 2020	December 31, 2019
	(In thousands)	
Finance leases	\$ 5,518	\$ 5,474
Laboratory equipment	2,830	2,844
Computer equipment	985	921
Office equipment and furniture	625	625
Total cost	9,958	9,864
Less accumulated depreciation and amortization	(6,849)	(6,035)
Total property and equipment, net	<u>\$ 3,109</u>	<u>\$ 3,829</u>

For the six months ended June 30, 2020 and 2019, depreciation and amortization expenses were \$0.8 million for both periods, respectively.

Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2020	December 31, 2019
	(In thousands)	
Contract research and development	\$ 9,206	\$ 24,107
Sales rebates, fees and discounts	5,737	10,870
Employee compensation	3,420	3,546
Consulting and professional fees	3,325	3,610
Interest payable	1,640	1,640
Clinical trials	1,629	1,982
Other accrued expenses	881	872
Total accrued expenses	<u>\$ 25,838</u>	<u>\$ 46,627</u>

Note 4—Fair-Value Measurements

As of June 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:

	June 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	14,124	—	—	14,124
Total	<u>\$ 15,278</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 15,278</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 \$2.0 million and \$3.1 million is excluded from our fair-value hierarchy disclosure as of June 30, 2020 and December 31, 2019, respectively. There were no unrealized gains or losses associated with our short-term investments as of June 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—Convertible Senior Notes” for the carrying amount and estimated fair value of our 6.25% Convertible Senior Notes due 2023.

Note 5—Debt

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

Note 6—Convertible Senior Notes

We have issued \$210.0 million aggregate principal amount 6.25% Convertible Senior Notes due 2023 (the Convertible Notes). The Convertible 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 Convertible Notes mature on November 15, 2023, unless earlier purchased, redeemed or converted in accordance with their terms.

The Convertible 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 Convertible Notes, we entered into a capped call transaction which essentially covers the number of shares of our common stock underlying the Convertible Notes when our common stock is trading between the initial

conversion price of \$19.22 per share and \$28.84 per share. As of June 30, 2020, all Convertible Notes remain outstanding.

The balance of our Convertible Notes at June 30, 2020 and December 31, 2019, is as follows:

	June 30, 2020	December 31, 2019
	(In thousands)	
Principal amount	\$ 210,000	\$ 210,000
Unamortized discount	(42,912)	(47,660)
Unamortized issuance costs attributable to principal amount	(3,716)	(4,127)
Total Convertible Notes, net	<u>\$ 163,372</u>	<u>\$ 158,213</u>

The estimated fair value of the Convertible Notes at June 30, 2020, as determined through consideration of quoted market prices, was \$216.6 million. The fair value is classified as Level 3 due to the limited trading activity for the Convertible Notes.

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:

	June 30, 2020	December 31, 2019
	(In thousands)	
Assets		
Operating lease assets	\$ 26,603	\$ 27,082
Finance lease assets, net	2,314	2,973
Total lease assets	<u>\$ 28,917</u>	<u>\$ 30,055</u>
Liabilities		
Current:		
Operating leases	\$ 2,503	\$ 2,282
Finance leases	1,199	1,222
Non-current:		
Operating leases	29,457	30,772
Finance leases	1,083	1,546
Total lease liabilities	<u>\$ 34,242</u>	<u>\$ 35,822</u>

The components of total lease cost are as follows:

	Six Months Ended June 30,	
	2020	2019
	(In thousands)	
Lease cost		
Operating lease cost	\$ 3,024	\$ 2,062
Finance lease cost:		
Amortization	703	646
Interest	159	169
Short-term lease cost	—	275
Variable lease cost	1,102	980
Sublease income	(602)	(447)
Total lease cost	<u>\$ 4,386</u>	<u>\$ 3,685</u>

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

	Six Months Ended	
	June 30,	
	2020	2019
	(In thousands)	
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows used for operating leases	\$ 4,284	\$ 3,301
Operating cash flows used for finance leases	\$ 159	\$ 169
Financing cash flows used for finance leases	\$ 530	\$ 545

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 June 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 \$49.8 million.

Contracts

We have various agreements with third parties that would collectively require payment of termination fees totaling \$18.1 million if we had cancelled the work as of June 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 during clinical development processes as well as low single to low double-digit royalties on the net income or net sales of the product. For the three and six months ended June 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 six months ended June 30, 2020, we received proceeds of \$2.8 million upon the exercise of stock options which resulted in the issuance of 315,048 shares of common stock. For the six months ended June 30, 2019, we received proceeds of \$1.7 million upon the exercise of stock options which resulted in the issuance of 184,365 shares of common stock.

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

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	<u>\$ 545</u>	<u>\$ 635,121</u>	<u>\$ (796,936)</u>	<u>\$ (161,270)</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	<u>\$ 492</u>	<u>\$ 558,157</u>	<u>\$ (688,923)</u>	<u>\$ (130,274)</u>

Note 10—Stock-Based Compensation

Stock-based compensation expense is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(In thousands)			
Research and development	\$ 1,631	\$ 1,646	\$ 3,078	\$ 3,140
Selling, general and administrative	2,191	1,952	4,220	3,833
Total	<u>\$ 3,822</u>	<u>\$ 3,598</u>	<u>\$ 7,298</u>	<u>\$ 6,973</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 June 30, 2020	Six Months Ended June 30, 2020
Estimated weighted-average fair value	\$ 10.23	\$ 8.22
Weighted-average assumptions:		
Expected volatility	81 %	77 %
Expected term, in years	6.0	6.0
Risk-free interest rate	0.72 %	1.11 %
Expected dividend yield	— %	— %

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

	Options Outstanding	Weighted- Average Exercise Price per Share	Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2019	11,207,931	\$ 11.72		
Granted	2,034,960	12.37		
Exercised	(315,048)	8.82		
Forfeited	(142,158)	14.32		
Balance at June 30, 2020	<u>12,785,685</u>	<u>\$ 11.87</u>	<u>6.2</u>	<u>\$ 41,036</u>
Vested and expected to vest at June 30, 2020	<u>12,336,369</u>	<u>\$ 11.81</u>	<u>6.1</u>	<u>\$ 40,291</u>
Exercisable at June 30, 2020	<u>8,712,170</u>	<u>\$ 11.17</u>	<u>4.9</u>	<u>\$ 34,089</u>

At June 30, 2020, there were 4.1 million unvested options outstanding that will vest over a weighted-average period of 2.7 years and 3.5 million shares were available to grant. The total estimated compensation expense yet to be recognized on outstanding options is \$31.4 million.

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. We have multiple Phase 3 and Phase 2 clinical-stage development programs in our pipeline, which are focused on: complement-mediated disorders, including hematopoietic stem cell transplant-associated thrombotic microangiopathy ("HSCT-TMA"), Immunoglobulin A ("IgA") nephropathy and atypical hemolytic uremic syndrome ("aHUS"), as well as addiction. 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.

Impact of Global Pandemic

The outbreak of the novel strain of coronavirus ("SARS-CoV-2") that causes the Coronavirus Disease 2019 ("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. Beginning in the second half of May 2020, cataract surgery resumed to varying degrees in locations throughout the country, generally under strict safety protocols. 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 continues to be limited, either by a need for time-consuming safety protocols, reduction in patient demand, or prohibition on elective surgical procedures in some localities, then there may be a corresponding reduction in demand for OMIDRIA. Additionally, 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 could 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 which, 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 for an additional two years, running from October 1, 2018 through September 30, 2020.

We are continuing to pursue permanent separate reimbursement for OMIDRIA beyond the currently scheduled expiration of pass-through reimbursement on September 30, 2020, but we can provide no assurance that these efforts will be successful. In its 2021 outpatient prospective payment system (“OPPS”) proposed rule, CMS confirmed the September 30, 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.

However, CMS is required under the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act to review OPSS 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 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. Based on these criteria, we believe that OMIDRIA will satisfy the criteria for separate payment when provided in the ASC setting once it again becomes packaged following expiration of its pass-through status, and that CMS is required to apply this policy to OMIDRIA as it has to another drug meeting these criteria. We intend to meet with HHS to seek separate payment for OMIDRIA when used in the ASC setting for the fourth quarter of 2020. 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 permanent separate payment or similar reimbursement for OMIDRIA beyond September 30, 2020; however, we cannot provide assurance that these efforts will be successful. 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. 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, which maintained the ongoing validity of the EMA for OMIDRIA. At this time, we do not expect to see significant sales of OMIDRIA in any countries within the EEA or other international territories.

Narsoplimab Developments

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, our investigational human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), to treat COVID-19 patients with ARDS, a severe and life-threatening symptom 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 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 and survived. 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 (ranging from 32% to 53%). A manuscript detailing the results of a study evaluating narsoplimab in patients with severe COVID-19 has been accepted for publication in the peer-reviewed journal of *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 ARDS associated with the disease. As we know through our work in HSCT-TMA, an endothelial injury syndrome, 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 mechanistic similarities between these two disorders. Narsoplimab has been shown to inhibit lectin pathway activation and block microvascular injury-associated thrombus formation as well as MASP-2-mediated activation of kallikrein and factor XII. We believe such anticoagulant effects may provide therapeutic benefits in both HSCT-TMA and COVID-19.

We currently are in discussions with agencies within the U.S. federal government regarding potential funding to accelerate large-scale manufacturing of narsoplimab to enable broader availability of narsoplimab for COVID-19 patients and for other COVID-19-related programmatic activities.

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 human monoclonal antibody targeting MASP-2, a novel pro-inflammatory protein target involved in activation of the complement system. The complement system 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 complement system can cause diseases characterized by serious tissue injury. MASP-2 is the effector enzyme of the lectin pathway of the complement system, and the current development focus for narsoplimab is diseases in which the lectin pathway has been shown to contribute to significant tissue injury and pathology. When not treated, these diseases are typically characterized by significant end organ injuries, such as kidney or central nervous system injury.

We have completed our pivotal clinical trial for narsoplimab in HSCT-TMA, and Phase 3 clinical programs are in process 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 received from the EC 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.

In October 2019, we initiated the rolling submission to FDA of our 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 submitted before beginning its review. The initial submission to FDA included all of the nonclinical (i.e., pharmacology, pharmacokinetics and toxicology) data, study reports, overview and summaries for the nonclinical sections of the BLA. Following the successful completion of manufacturing of the required process validation lots of narsoplimab, we submitted in April 2020 the second part of the BLA containing information related to the chemistry, manufacturing and controls (“CMC”) for narsoplimab. The remaining CMC information for the BLA was submitted to FDA in early August 2020. The clinical sections of the BLA are being prepared for submission and, once all analyses are complete and compiled, these remaining parts of the BLA will be submitted.

In March 2020, we reported clinical data from our pivotal trial of narsoplimab in HSCT-TMA. The single-arm, open-label trial included safety and efficacy endpoints that were previously agreed to with FDA. These 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 LDH, levels, while improvement in clinical status was evaluated based on organ function and transfusions. Patients who did not fully meet these criteria were considered “non-responders.”

The FDA-agreed efficacy threshold for the primary endpoint is a complete response rate of 15%. Among patients who received at least one dose of narsoplimab, the complete response rate was 54% ($p < 0.0001$), while the complete response rate among patients who received the protocol-specified narsoplimab treatment of at least four weeks of dosing was 65% ($p < 0.0001$).

Secondary endpoints in the trial were survival rates and change from baseline in HSCT-TMA laboratory markers. Among the responder population, 93% of patients survived for at least 100 days following HSCT-TMA diagnosis, while 83% of patients who received treatment for at least four weeks and 68% of the total treated population achieved this endpoint. 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. Patients in the trial had a high expected mortality rate, with 93% of them having multiple risk factors. 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 plan to complete the submission of an MAA after our BLA submission has been filed with FDA. We are targeting to complete our MAA submission in the first half of 2021. In October 2019 we received a positive opinion from EMA on our pediatric investigation plan ("PIP") for narsoplimab in the treatment of HSCT-TMA. A PIP outlining a development program for the investigational product in the pediatric population must be agreed with EMA as a prerequisite to EMA's acceptance of an MAA. The narsoplimab PIP provides a study plan to evaluate the safety and effectiveness of the drug for HSCT-TMA in patients from one month through 17 years of age. We received a deferral for completion of our PIP until after approval of the narsoplimab MAA.

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.

- PDE7 - OMS52Z. 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.

- 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; Bechet’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 June 2020 we submitted a Clinical Trial Application (“CTA”) to European regulators to initiate clinical trials evaluating OMS906, the company’s lead human monoclonal antibody from its MASP-3 program. For maximum flexibility in the conduct of our OMS906 clinical trials and to ensure timely progress of our OMS906 program, we also submitted an IND application to FDA to initiate clinical trials evaluating OMS906 in the United States. Assuming positive regulatory review of the CTA or IND, as applicable, we plan to initiate the Phase 1 clinical trial evaluating OMS906 in either the United States or Europe, based on the earliest availability of clinical testing sites. We currently expect to begin enrollment in the Phase 1 trial in September. The Phase 1 clinical trial will be a placebo-controlled, double-blind, single-ascending-dose and multiple-ascending-dose study to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of OMS906 administered subcutaneously and intravenously to healthy subjects. Following adequate collection and analysis in the Phase 1 study data, the initial Phase 2 study for OMS906 is expected to be conducted in patients with paroxysmal nocturnal hemoglobinuria (PNH), a rare, acquired, life-threatening disease of the blood.

Preclinical Development Programs and Platforms

Our preclinical programs and platforms include:

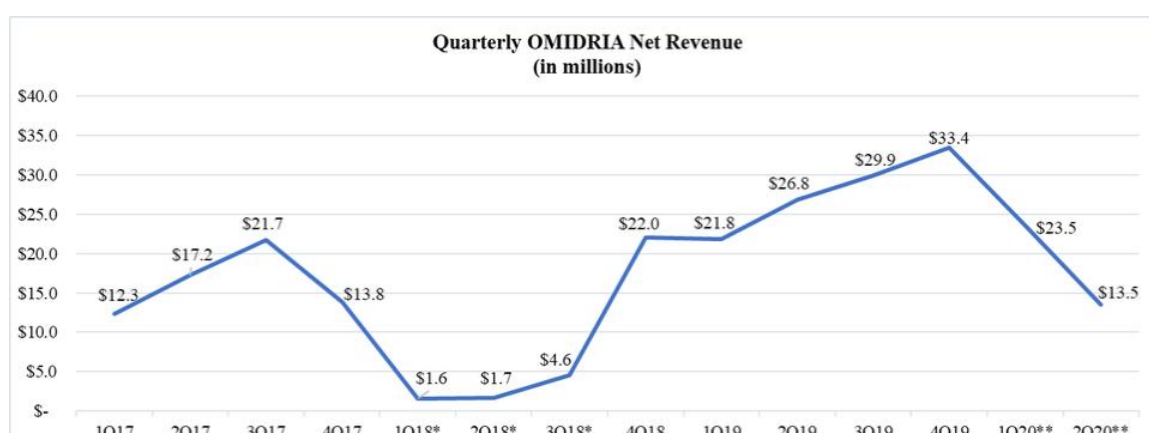
- *Other MASP Inhibitor Preclinical Programs.* We have generated positive preclinical data from MASP-2 inhibition in *in vivo* models of age-related macular degeneration, myocardial infarction, diabetic neuropathy, stroke, ischemia-reperfusion injury, and other diseases and disorders. We are also developing a longer-acting second generation antibody targeting MASP-2, which we are targeting for initiation of clinical trials in 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. 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 \$33.3 million and \$14.5 million for the three months ended June 30, 2020 and 2019, respectively, and our OMIDRIA revenues were \$13.5 million and \$26.8 million for the same periods. As of June 30, 2020, we had \$16.1 million in cash and cash equivalents and short-term investments available for general corporate use and \$15.8 million in accounts receivable, net.

We expect our net losses will continue until such time as we derive sufficient revenues from sales of OMIDRIA and/or other sources, such as licensing, product sales and other revenues from our product candidates, 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

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 Q4 2018, our revenues quickly returned to levels when separate reimbursement was available and 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. Beginning in the second half of May 2020, cataract procedures resumed to varying degrees in locations throughout the country. By the end of June 2020, the run rate of weekly OMIDRIA sales approximated those seen prior to the pandemic.

In its 2021 OPPTS proposed rule, CMS confirmed the September 30, 2020 expiration of pass-through reimbursement for OMIDRIA. However, 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 has 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. Based on these criteria, we believe that OMIDRIA will satisfy the criteria

for separate payment when provided in the ASC setting once it again becomes packaged following expiration of its pass-through status. We are also continuing to pursue other administrative and legislative avenues to secure permanent separate payment or similar reimbursement for OMIDRIA beyond September 30, 2020. 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 pass-through reimbursement status for OMIDRIA.

COVID-19 and uncertainty around pass-through status for OMIDRIA could have a continuing adverse impact on our business, operations and financial results, limiting the number of cataract procedures which may be performed and 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 following the scheduled expiration of pass-through status on September 30, 2020, 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(In thousands)		(In thousands)	
Product sales, net	\$ 13,530	\$ 26,753	\$ 37,067	\$ 48,532

During the three and six months ended June 30, 2020, OMIDRIA revenue was \$13.5 million and \$37.1 million as compared to \$26.8 million and \$48.5 million for the three and six months ended June 30, 2019. The decrease in revenue during the three and six months ended June 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 beginning in mid-March 2020. In early May, a large number of states began re-opening, and, by the end of June 2020 the weekly run rate of OMIDRIA sales had returned to levels approaching those seen prior to the pandemic. Given the uncertainty and local variances in the severity and response to the COVID-19 pandemic across the U.S., and the future of pass-through reimbursement, 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 six months ended June 30, 2020 was 14.6% and 26.8% of gross OMIDRIA product sales. This compares to 28.2% and 27.7% for the three and six months ended June 30, 2019. The decrease in gross-to-net deductions as a percentage of sales compared to the three months ended June 30, 2019 is primarily due to the reversal of \$2.4 million of product return allowances which were originally recorded in Q1 2020 to account for potential product returns due to the postponement of elective surgical procedures, including cataract surgery due to the COVID-19 pandemic. The reserve was eliminated in Q2 2020 due to the resumption of cataract procedures in mid-May 2020.

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

	<u>Chargebacks and Rebates</u>	<u>Distribution Fees and Product Return Allowances (In thousands)</u>	<u>Total</u>
Balance as of December 31, 2019	\$ 10,240	\$ 2,237	\$ 12,477
Provisions	11,534	2,022	13,556
Payments	(16,086)	(3,147)	(19,233)
Balance as of June 30, 2020	<u>\$ 5,688</u>	<u>\$ 1,112</u>	<u>\$ 6,800</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. Additionally, if separate reimbursement for OMIDRIA does not last beyond September 30, 2020, it is possible that wholesalers, ASCs and hospitals may return a portion of their OMIDRIA on hand for a full refund of the purchase price. If a reserve is required, we would record the reserve during our third quarter of 2020.

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(In thousands)		(In thousands)	
Direct external expenses:				
Clinical research and development:				
MASP-2 Program - OMS721 (narsoplimab)	\$ 9,720	\$ 5,058	\$ 22,935	\$ 19,495
OMIDRIA - Ophthalmology	433	379	884	1,087
PDE7 - OMS527	259	603	1,596	1,179
Total clinical research and development	10,412	6,040	25,415	21,761
Preclinical research and development	3,144	2,102	6,834	3,617
Total direct external expenses	13,556	8,142	32,249	25,378
Internal, overhead and other expenses	8,945	9,320	17,716	16,845
Stock-based compensation expense	1,631	1,646	3,078	3,140
Total research and development expenses	\$ 24,132	\$ 19,108	\$ 53,043	\$ 45,363

Total direct clinical research and development expenses increased \$4.4 million and \$3.7 million for the three and six months ended June 30, 2020 compared to the same periods in 2019. The \$4.4 million increase for the three months ended June 30, 2020 is due to higher narsoplimab manufacturing costs and increased costs supporting the preparation of our rolling BLA for HSCT-TMA in the U.S. The increase for the six months ended June 30, 2020 is due to increased IgA nephropathy clinical trial costs as well as higher costs supporting the preparation of our rolling BLA in HSCT-TMA and the increased medical affairs activities.

The \$1.0 million and \$3.2 million increase in our preclinical research and development expense for the three and six months ended June 30, 2020 as compared to the same periods in 2019 reflects additional third-party manufacturing scale up costs related to our OMS906 program as well as development and analytical activities related our MASP-2 long-acting second-generation antibody program.

We expect the majority of our research and development expenses for the remainder of 2020 to be related to our narsoplimab program. We expect research and development costs to increase in 2020 as we incur incremental manufacturing costs in preparation for the anticipated commercial launch of narsoplimab in HSCT-TMA in the U.S.

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		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
	(In thousands)		(In thousands)	
Selling, general and administrative expenses, excluding stock-based compensation expense	\$ 14,740	\$ 14,976	\$ 30,747	\$ 27,727
Stock-based compensation expense	2,191	1,952	4,220	3,833
Total selling, general and administrative expenses	<u>\$ 16,931</u>	<u>\$ 16,928</u>	<u>\$ 34,967</u>	<u>\$ 31,560</u>

The increase in selling, general and administrative expenses during the six months ended June 30, 2020 compared to the same periods in 2019 was primarily due to increased pre-commercialization marketing activities for narsoplimab, including employee-related costs and professional service fees.

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

Interest Expense

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
	(In thousands)		(In thousands)	
Interest expense	\$ 5,978	\$ 5,530	\$ 11,880	\$ 11,130

Interest expense is comprised of interest related to our \$210.0 million of 6.25% Convertible Senior Notes due 2023 (the "Convertible Notes"). Non-cash interest expense for the three and six months ended June 30, 2020 was \$2.6 million and \$5.2 million, respectively. For more information regarding our Convertible Notes, see Part II, Item 8, "Note 8-- Convertible Senior Notes" in [our Annual Report on Form 10-K for the year ended December 31, 2019](#).

Financial Condition - Liquidity and Capital Resources

As of June 30, 2020, we had \$16.1 million in cash, cash equivalents and short-term investments available for general corporate use held primarily in money-market accounts as compared to \$60.8 million at December 31, 2019. In addition, as of June 30, 2020, we had \$15.8 million in accounts receivable, net. We have historically generated net losses and incurred negative cash flows from operations and debt service. For the six months ended June 30, 2020, we incurred net losses of \$62.3 million and incurred negative cash flows from operations of \$46.7 million. We expect to continue to incur losses from operations until our revenues exceed operating costs and debt service obligations.

In the second quarter of 2020, our business operations and liquidity continued to be negatively affected by the reduction in demand for OMIDRIA caused by restrictions on the number of elective surgical procedures which could be performed. The continued increase in the number of COVID-19 cases within the U.S. may lead to further restrictions on elective surgeries going forward. This may continue to negatively impact our ability to cover our expenses in future periods, with the magnitude being dependent on the duration and extent of applicable limitations placed on the operations of our ASC and hospital customers.

In mid-May, a large number of states began re-opening ASCs and hospitals to cataract surgery with a number of our customers re-ordering OMIDRIA from our wholesalers. We cannot yet predict with certainty the levels of OMIDRIA product sales we will achieve. In addition, pass-through reimbursement for OMIDRIA is currently scheduled to expire on September 30, 2020. We are pursuing legislative and administrative means to extend permanent reimbursement but have not yet received such an extension. However, regardless of whether we secure continued pass-through treatment for OMIDRIA, our working capital needs are likely to continue to increase, particularly if the disruption to our operations caused by the COVID-19 pandemic continues. Consequently, we are unable to include these factors in the determination regarding our prospects as a going concern.

OMIDRIA revenues and amounts available under the Line of Credit Agreement with Silicon Valley Bank, are determined based on eligible OMIDRIA accounts receivable, less certain reserves. As of August 7, 2020, we were eligible to borrow approximately \$6.6 million under the Line of Credit Agreement. We have also not included any proceeds from debt transactions or other financing instruments in our analysis of our ability to continue as a going concern, despite our successful track record in accessing capital through each of these avenues nor any potential partnerships related to our products or product candidates. The conditions described above when evaluated within the constraints of the accounting literature raise substantial doubt with respect to our ability to meet our obligations through August 10, 2021 and, therefore, to continue as a going concern.

We plan to continue to fund our operations through proceeds from sales of OMIDRIA, and we may utilize funds available under our receivable-based line of credit to the extent it is available to us. Should it be necessary or determined to be strategically advantageous, we may 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. If these capital sources, for any reason, are needed but inaccessible, it would have a significantly negative effect on our financial condition. 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

	<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>
	(In thousands)	
<u>Selected cash flow data</u>		
Cash provided by (used in):		
Operating activities	\$ (46,738)	\$ (29,537)
Investing activities	\$ 43,370	\$ 26,499
Financing activities	\$ 2,248	\$ 1,163

Operating Activities. Net cash used in operating activities for the six months ended June 30, 2020 increased by \$17.2 million as compared to the same period in 2019. The net increase is primarily due to an increase in our net loss of \$23.5 million and an increase of \$20.1 million in cash used in accounts payable and accrued expense offset by a \$25.1 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 provided by investing activities during the six months ended June 30, 2020 was \$43.4 million, an increase of \$16.9 million for the same period in 2019 driven by an increase in proceeds from sale and maturities of investments of \$19.5 million offset by purchases of \$2.7 million.

Financing Activities. Net cash provided by financing activities during the six months ended June 30, 2020 was \$2.2 million, an increase of \$1.1 million compared to the same period in 2019. The increase for the six months ended June 30, 2020 compared to the prior year was due to incremental proceeds from exercises of stock options.

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 June 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 June 30, 2020.

	Payments Due Within				Total
	1 Year	2-3 Years	4-5 Years	More than 5 Years	
Operating leases	\$ 3,210	\$ 13,214	\$ 13,795	\$ 19,590	\$ 49,809
Finance leases (principal and interest)	697	1,693	152	—	2,542
Unsecured convertible senior notes	6,563	26,250	223,125	—	255,938
Goods & services	17,621	429	54	—	18,104
Total	<u>\$ 28,091</u>	<u>\$ 41,586</u>	<u>\$ 237,126</u>	<u>\$ 19,590</u>	<u>\$ 326,393</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 June 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 \$49.8 million.

Convertible Notes

For more information regarding our Convertible Notes, see Part II, Item 8, “Note 8--Convertible Senior Notes” in [our Annual Report on Form 10-K for the year ended December 31, 2019](#).

Goods and Services

We have certain other non-cancelable obligations under various agreements that relate to goods and services. As of June 30, 2020, our aggregate firm commitments were \$18.1 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 June 30, 2020, we had cash, cash equivalents and short-term investments of \$16.1 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 June 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 June 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 may be materially adversely affected, and the price of our common stock may decline.

OMIDRIA is our only product that has been approved by the FDA, for commercial sale in the U.S. For the three months ended June 30, 2020, we recorded net sales of OMIDRIA of \$13.5 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. 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 scheduled expiration of pass-through reimbursement on September 30, 2020 and uncertainty regarding the extent of coverage and reimbursement for OMIDRIA when used in Medicare patients after September 30, 2020;
- 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.

In the event that pass-through status for OMIDRIA expires on September 30, 2020 and we are not able to secure separate payment or similar reimbursement for OMIDRIA, or if there is a delay between September 30, 2020 and when we are able to secure 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.

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 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 there may 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 six COVID-19 patients with ARDS. While all six COVID-19 patients treated with narsoplimab survived and recovered, and we believe the results observed following narsoplimab treatment in severe COVID-19 cases were consistent with those seen in HSCT-TMA, we cannot provide assurance that we will be able to evaluate narsoplimab in additional COVID-19 patients, or that the results observed in the compassionate use program will be observed in any future study of narsoplimab for this indication. We may be unable to design and conduct a large-scale clinical trial evaluating narsoplimab in COVID-19 or otherwise access and treat additional COVID-19 patients, we may be unable to 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 we may be unable to 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.

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- 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
10.1	First Amendment to Loan and Security Agreement, dated as of August 7, 2020, by and between Omeros Corporation and Silicon Valley Bank
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

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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: August 10, 2020

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

Dated: August 10, 2020

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

**FIRST AMENDMENT
TO
LOAN AND SECURITY AGREEMENT**

This First Amendment to Loan and Security Agreement (this “Amendment”) is entered into this 7th day of August, 2020, by and between **SILICON VALLEY BANK** (“Bank”) and **OMEROS CORPORATION**, a Washington corporation (“Borrower”) whose address is 201 Elliott Avenue West, Seattle, Washington 98119.

RECITALS

A. Bank and Borrower have entered into that certain Loan and Security Agreement dated as of August 2, 2019 (as the same may from time to time be amended, modified, supplemented or restated, the “Loan Agreement”).

B. Bank has extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower wishes to issue and sell, in one or more offerings, unsecured convertible notes in an aggregate principal amount of up to Three Hundred Fifty Million Dollars (\$350,000,000.00).

D. Borrower has requested that Bank amend the Loan Agreement to make certain revisions to the Loan Agreement as more fully set forth herein.

E. Bank has agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

Now, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 7.7 (Distributions; Investments). Section 7.7 of the Loan Agreement is amended by deleting the word “and” immediately preceding clause (a)(vii) and inserting the following new clause (viii) at the end thereof:

“(viii) purchase, redeem, retire, or otherwise acquire shares of its capital stock or other equity interests in connection with any forward transactions, options, warrants or other rights to acquire capital stock of Borrower entered into by

Borrower substantially concurrently with its issuance of convertible securities on or before September 30, 2020;”

2.2 Section 13 (Definitions). Section 13.1 of the Loan Agreement is amended by deleting subsection (h) in the definition of Permitted Indebtedness in its entirety and inserting in lieu thereof the following:

“ (h) unsecured Indebtedness which by its terms is convertible into equity securities of Borrower (the “**Permitted Convertible Debt**”) provided that (i) the aggregate principal amount of the Permitted Convertible Debt shall not exceed (A) prior to September 1, 2020, Five Hundred Fifty Million Dollars (\$550,000,000.00) at any time outstanding, and (B) on September 1, 2020 and at all times thereafter, Three Hundred Fifty Million Dollars (\$350,000,000.00) at any time outstanding (ii) no scheduled principal payments may be made with respect to the Permitted Convertible Debt, and (iii) if a default or an event of default (however defined) has occurred and is continuing under the Permitted Convertible Debt (“**Permitted Convertible Debt Default**”), all outstanding liabilities and obligations of Borrower to Bank shall be immediately be repaid in full;”

3. Limitation of Amendments.

3.1 The amendments set forth in Section 2, above, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Bank may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Bank to enter into this Amendment, Borrower hereby represents and warrants to Bank as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Bank on the

Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Release by Borrower:

A. FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves, releases, and discharges Bank and its present or former employees, officers, directors, agents, representatives, attorneys (collectively, the "**Releasees**"), and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, that Borrower may have against the Releasees which arise out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Amendment (collectively "**Released Claims**").

Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

B. In furtherance of this release, Borrower expressly acknowledges and waives any and all rights under Section 1542 of the California Civil Code, which provides as follows:

“A **general release** does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party.” (Emphasis added.)

C. By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all Released Claims; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever.

Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Bank with respect to the facts underlying this release or with regard to any of such party’s rights or asserted rights.

D. This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Bank to enter into this Amendment, and that Bank would not have done so but for Bank’s expectation that such release is valid and enforceable in all events.

E. Borrower hereby represents and warrants to Bank, and Bank is relying thereon, as follows:

1 Except as expressly stated in this Amendment, neither Bank nor any agent, employee or representative of Bank has made any statement or representation to Borrower regarding any fact relied upon by Borrower in entering into this Amendment.

2 Borrower has made such investigation of the facts pertaining to this Amendment and all of the matters appertaining thereto, as it deems necessary.

3 The terms of this Amendment are contractual and not a mere recital.

4 This Amendment has been carefully read by Borrower, the contents hereof are known and understood by Borrower, and this Amendment is signed freely, and without duress, by Borrower.

5 Borrower represents and warrants that it is the sole and lawful owner of all right, title and interest in and to every Released Claim, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person,



firm or entity any Released Claim. Borrower shall indemnify Bank, defend and hold it harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

6. Integration. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

7. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

8. Effectiveness. This Amendment shall be deemed effective upon (a) the due execution and delivery to Bank of this Amendment by each party hereto, and (b) Borrower's payment to Bank of Bank's legal fees and expenses incurred in connection with the negotiation and preparation of this Amendment.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BANK

BORROWER

SILICON VALLEY BANK

OMEROS CORPORATION

By: /s/ Shawn Parry
Name: Shawn Parry
Title: Managing Director

By: /s/ Michael A. Jacobsen
Name: Michael A. Jacobsen
Title: Chief Accounting Officer

**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: August 10, 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: August 10, 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 June 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: August 10, 2020

/s/ Gregory A. Demopoulos

Gregory A. Demopoulos, 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 June 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: August 10, 2020

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer
