
**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, 2019
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)

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, as amended, 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 ☒

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

Common Stock, \$0.01 par value per share
(Title of each class)

OMER
(Trading symbol)

The Nasdaq Stock Market LLC
(Name of each exchange on which registered)

As of August 5, 2019, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 49,287,597.

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 relating to demand for OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% from wholesalers, ambulatory surgery centers (ASCs) and hospitals, and our expectations regarding OMIDRIA product sales;
 - our plans for the marketing and distribution of OMIDRIA and our estimates of OMIDRIA chargebacks and rebates, distribution fees and product returns;
 - 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 related to obtaining a permanent separate or similar reimbursement for OMIDRIA from the Centers for Medicare & Medicaid Services (CMS), particularly for periods after September 30, 2020, and our expectations regarding reimbursement coverage for OMIDRIA by commercial and government payers;
 - our expectations regarding the clinical, therapeutic and competitive benefits and importance of OMIDRIA and our product candidates;
 - our ability to design, initiate and/or 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 OMS527 and OMS906;
 - in 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 and/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/or EMA in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), Immunoglobulin A (IgA) nephropathy, and atypical hemolytic uremic syndrome (aHUS);
 - whether and when a Biologics License Application (BLA) may be filed with the FDA for narsoplimab in any indication and whether the FDA will grant accelerated or regular (full) approval for narsoplimab in any indication;
 - 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 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, 2019

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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)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,986	\$ 5,861
Short-term investments	27,859	54,637
Receivables, net	28,515	22,818
Inventory	1,187	88
Prepaid expense and other assets	4,397	6,463
Total current assets	65,944	89,867
Property and equipment, net	4,183	3,845
Right of use assets	17,318	—
Restricted investments	1,154	1,154
Advanced payments, non-current	1,161	1,070
Total assets	\$ 89,760	\$ 95,936
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	\$ 6,260	\$ 6,281
Accrued expenses	31,777	30,186
Current portion of lease liabilities	2,636	889
Total current liabilities	40,673	37,356
Lease liabilities, non-current	25,945	1,578
Unsecured convertible senior notes, net	153,416	148,981
Deferred rent	—	8,177
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, 2019 and December 31, 2018.	—	—
Common stock, par value \$0.01 per share, 150,000,000 shares authorized at June 30, 2019 and December 31, 2018; 49,196,049 and 49,011,684 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively.	492	490
Additional paid-in capital	558,157	549,479
Accumulated deficit	(688,923)	(650,125)
Total shareholders' deficit	(130,274)	(100,156)
Total liabilities and shareholders' deficit	\$ 89,760	\$ 95,936

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,	
	2019	2018	2019	2018
Revenue:				
Product sales, net	\$ 26,753	\$ 1,655	\$ 48,532	\$ 3,244
Costs and expenses:				
Cost of product sales	55	116	186	319
Research and development	19,108	19,412	45,363	37,551
Selling, general and administrative	16,928	12,744	31,560	23,678
Total costs and expenses	36,091	32,272	77,109	61,548
Loss from operations	(9,338)	(30,617)	(28,577)	(58,304)
Interest expense	(5,530)	(3,676)	(11,130)	(6,502)
Other income	415	597	909	1,056
Net loss	\$ (14,453)	\$ (33,696)	\$ (38,798)	\$ (63,750)
Comprehensive loss	\$ (14,453)	\$ (33,696)	\$ (38,798)	\$ (63,750)
Basic and diluted net loss per share	\$ (0.29)	\$ (0.70)	\$ (0.79)	\$ (1.32)
Weighted-average shares used to compute basic and diluted net loss per share	49,084,093	48,384,460	49,048,432	48,333,610

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Six Months Ended June 30,	
	2019	2018
Operating activities:		
Net loss	\$ (38,798)	\$ (63,750)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,973	5,966
Non-cash interest expense	4,435	2,503
Depreciation and amortization	827	429
Changes in operating assets and liabilities:		
Receivables	(5,697)	15,615
Inventory	(1,099)	208
Prepaid expenses and other assets	1,975	(930)
Accounts payable and accrued expenses	1,847	(2,247)
Net cash used in operating activities	(29,537)	(42,206)
Investing activities:		
Purchases of property and equipment	(279)	(386)
Purchases of investments	(472)	(45,166)
Proceeds from the sale and maturities of investments	27,250	40,000
Net cash provided by (used in) investing activities	26,499	(5,552)
Financing activities:		
Proceeds from borrowings under notes payable	—	44,550
Proceeds upon exercise of stock options and warrants	1,708	2,877
Release in restricted investments	—	56
Payments on finance lease liabilities	(545)	(236)
Net cash provided by financing activities	1,163	47,247
Net decrease in cash and cash equivalents	(1,875)	(511)
Cash and cash equivalents at beginning of period	5,861	3,394
Cash and cash equivalents at end of period	\$ 3,986	\$ 2,883
Supplemental cash flow information		
Cash paid for interest	\$ 6,731	\$ 3,999
Conversion of accrued interest to notes payable	\$ —	\$ 1,909
Property acquired under finance lease	\$ 886	\$ 358

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, 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 inter-company 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, 2019 and December 31, 2018 and for the three and six months ended June 30, 2019 and 2018 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2018 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, 2018, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 1, 2019.

We continue to advance a series of clinical and preclinical programs (including three programs currently in Phase 3). The Centers for Medicare & Medicaid Services (CMS) granted transitional pass-through reimbursement status for OMIDRIA from January 1, 2015 through December 31, 2017 for patients covered by Medicare Part B. On October 1, 2018, OMIDRIA pass-through reimbursement was reinstated for a two-year period and OMIDRIA net sales are at record levels. We believe OMIDRIA sales will continue to grow throughout the remainder of 2019 and into 2020. While we believe that OMIDRIA will obtain permanent separate payment beyond the scheduled expiration of pass-through reimbursement on September 30, 2020, we cannot at this time predict with precision the extent or duration of growth in OMIDRIA revenues. As a result, despite our record OMIDRIA sales, meaningful growth in OMIDRIA sales in the second half of 2019 and 2020 are not included in the determination regarding our prospects as a going concern. Similarly, we are unable to include in the determination amounts available under our revolving 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. 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 8, 2020 and, therefore, to continue as a going concern.

We plan to continue to fund a portion of our operations through proceeds from sales of OMIDRIA and, if necessary, through other revenue sources and financial instruments as noted above. If these capital sources, for any reason, are needed but inaccessible, it would have a significantly negative effect 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, and/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 contingencies. We base our estimates on historical experience and on various other factors 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.

Product Sales, Net

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

On January 1, 2019, we adopted Accounting Standards Update (ASU) 2016-02, *Leases*, (Topic 842) using a modified retrospective approach versus recasting the prior periods presented. We elected the package of practical expedients permitted under the transition guidance, which allowed us to carryforward our historical assessment of whether (i) contracts contain leases, (ii) lease classifications and (iii) initial direct costs. Upon adoption we recognized right-of-use assets and lease liabilities of \$17.7 million and \$26.4 million, respectively, in our Consolidated Balance Sheet. The balance of the net right-of-use asset included the reversal of the outstanding balance of deferred rent of \$8.7 million.

We record operating leases on our Consolidated Balance Sheet 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 on our Consolidated Balance Sheet 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

On January 1, 2019, we adopted ASU 2018-07, *Compensation — Stock Compensation*, (Topic 958) which simplifies the accounting for share-based payments granted to non-employees for services by aligning it with the accounting for share-based payments to employees and directors, with certain exceptions. The adoption was immaterial to our consolidated financial statements.

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.

Recent Accounting Pronouncement Not Yet Adopted

In June 2016, the Financial Accounting Standards Board (FASB) 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 expect to adopt the standard on January 1, 2020 and are still in the process of evaluating the effect of adoption 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, 2019 and 2018 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,	
	2019	2018
Outstanding options to purchase common stock	11,800,959	10,542,066
Outstanding warrants to purchase common stock	243,115	300,602
Total potentially dilutive shares excluded from loss per share	<u>12,044,074</u>	<u>10,842,668</u>

Note 3—Certain Balance Sheet Accounts

Accounts Receivable, net

Accounts receivable, net consist of the following:

	June 30, 2019	December 31, 2018
	(In thousands)	
Trade receivables, net	\$ 28,381	\$ 22,654
Sublease and other receivables	134	164
Total accounts receivables, net	<u>\$ 28,515</u>	<u>\$ 22,818</u>

Trade receivables are shown net of \$2.1 million and \$0.4 million of chargeback and product return allowances as of June 30, 2019 and December 31, 2018, respectively.

Inventory

Inventory consists of the following:

	June 30, 2019	December 31, 2018
	(In thousands)	
Raw materials	\$ 43	\$ 83
Work-in-progress	558	—
Finished goods	586	5
Total inventory	<u>\$ 1,187</u>	<u>\$ 88</u>

Property and Equipment, Net

Property and equipment, net consists of the following:

	June 30, 2019	December 31, 2018
	(In thousands)	
Finance leases	\$ 4,920	\$ 4,034
Laboratory equipment	2,789	2,569
Computer equipment	921	862
Office equipment and furniture	625	625
Total cost	9,255	8,090
Less accumulated depreciation and amortization	(5,072)	(4,245)
Total property and equipment, net	<u>\$ 4,183</u>	<u>\$ 3,845</u>

For the six months ended June 30, 2019 and 2018, depreciation and amortization expenses were \$0.8 million and \$0.4 million, respectively.

Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2019	December 31, 2018
	(In thousands)	
Contract research and development	\$ 12,085	\$ 12,012
Sales rebates, fees and discounts	8,349	8,075
Employee compensation	5,336	2,714
Consulting and professional fees	2,607	3,669
Interest payable	1,641	1,677
Clinical trials	958	820
Other accrued expenses	801	1,219
Total accrued expenses	<u>\$ 31,777</u>	<u>\$ 30,186</u>

Note 4—Fair-Value Measurements

As of June 30, 2019, and December 31, 2018, 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, 2019			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	\$ 1,154	\$ —	\$ —	\$ 1,154
Money-market funds classified as short-term investments	27,859	—	—	27,859
Total	<u>\$ 29,013</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 29,013</u>

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	\$ 1,154	\$ —	\$ —	\$ 1,154
Money-market funds classified as short-term investments	54,637	—	—	54,637
Total	\$ 55,791	\$ —	\$ —	\$ 55,791

Cash held in demand deposit accounts of \$4.0 million and \$5.9 million is excluded from our fair-value hierarchy disclosure as of June 30, 2019 and December 31, 2018, respectively. There were no unrealized gains or losses associated with our short-term investments as of June 30, 2019 or December 31, 2018. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets for receivables, accounts payable, other current monetary assets and liabilities approximate fair value.

Note 5—Notes Payable

In October 2016, we entered into a term loan agreement with CRG Servicing LLC (the CRG Loan) and, in November 2016, borrowed \$80.0 million. In May 2018, we borrowed the remaining \$45.0 million available under the CRG Loan and issued warrants to purchase up to 200,000 shares of our common stock with an exercise price of \$23.00 per share. The warrants have a five-year term and remained outstanding as of June 30, 2019.

In November 2018, we issued unsecured convertible senior notes (see Note 6 - “Convertible Senior Notes”) and repaid the CRG Loan. Upon repayment, we incurred a loss on early extinguishment of debt of \$13.0 million.

In August 2019, we entered into a Loan and Security Agreement with Silicon Valley Bank (the SVB Loan Agreement), which provides for a \$50 million revolving line of credit facility. Under the SVB Loan Agreement we may draw at our discretion, on a revolving basis, up to the lesser of \$50 million and a borrowing base of 85% of eligible accounts receivable, less certain reserves. The SVB Loan Agreement does not encumber any of our intellectual property or development program inventories; our obligations under the SVB Loan Agreement are secured by our remaining assets.

Note 6—Convertible Senior Notes

On November 15, 2018, we issued at face value \$210.0 million aggregate principal amount of our 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, beginning on May 15, 2019.

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. As of June 30, 2019, all Convertible Notes remain outstanding.

The balance of our Convertible Notes at June 30, 2019 and December 31, 2018, is as follows:

	June 30, 2019	December 31, 2018
	(In thousands)	
Principal amount	\$ 210,000	\$ 210,000
Unamortized discount	(52,074)	(56,156)
Unamortized issuance costs attributable to principal amount	(4,510)	(4,863)
Total Convertible Notes, net	<u>\$ 153,416</u>	<u>\$ 148,981</u>

For more details on 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, 2018.

Note 7—Lease Liabilities

We have operating leases related to our office and laboratory space. The initial term of the leases is through November 2027 and we have two options to extend the lease term, each by five years. We have finance leases for certain laboratory and office equipment that have lease terms expiring through December 2021.

As described further in Note 1 – Organization and Significant Accounting Policies, on January 1, 2019, we adopted ASU 2016-02, *Leases*, (Topic 842) using a modified retrospective approach versus recasting the prior periods presented. The lease-related assets and liabilities recorded on the balance sheet are as follows. Prior year interim financial statements were not recast under the new standard and, therefore, those amounts are not presented below.

	Classification on the Balance Sheet	June 30, 2019 (In thousands)
Assets		
Operating lease assets	Right of use assets	\$ 17,318
Finance lease assets	Property and equipment, net	3,113
Total lease assets		<u>\$ 20,431</u>
Liabilities		
Current:		
Operating Leases	Current portion of lease liabilities	\$ 1,488
Finance Lease	Current portion of lease liabilities	1,148
Non-current:		
Operating	Lease liability, non-current	24,284
Finance	Lease liability, non-current	1,661
Total lease liabilities		<u>\$ 28,581</u>
Weighted-average remaining lease term		
Operating leases		8.3 years
Finance leases		2.2 years
Weighted-average discount rate		
Operating leases (1)		12.85 %
Finance leases		12.28 %

(1) Upon adoption of ASU 2016-02, *Leases*, (Topic 842) the discount rate used for existing operating leases was established at January 1, 2019 and represents our incremental borrowing rate.

The components of total lease costs are as follows:

	Six Months Ended June 30, 2019 (In thousands)
Lease cost	
Operating lease cost	\$ 2,062
Finance lease cost:	
Amortization	646
Interest	169
Short-term lease cost	275
Variable lease costs	980
Sublease income	(447)
Total lease cost	<u>\$ 3,685</u>

The supplemental cash flow information related to leases during 2019 is as follows:

Cash paid for amounts included in the measurement of lease liabilities

Operating cash flows used for operating leases	\$	3,301
Operating cash flows used for finance leases	\$	169
Financing cash flows used for finance leases	\$	545

The future maturities of our lease liabilities as of June 30, 2019 are as follows:

	Operating Leases	Finance Leases
	(In thousands)	
2019	\$ 2,339	\$ 688
2020	4,770	1,245
2021	4,880	887
2022	4,995	293
2023	5,112	97
Thereafter	20,726	—
Total undiscounted lease payments	42,822	3,210
Less interest	17,051	400
Lease liabilities	\$ 25,771	\$ 2,810

As of June 30, 2019, we have committed to additional leased space in The Omeros Building that will commence in September and October 2019. The expected lease term is approximately seven years and the monthly lease payments are approximately \$0.1 million over the expected lease term.

Note 8—Commitments and Contingencies

Contracts

We have various agreements with third parties that would collectively require payment of termination fees totaling \$20.4 million as of June 30, 2019 if we cancel the work within specific time frames, either prior to commencing or during performance of the contracted services.

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 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, 2019 and the year ended December 31, 2018, development milestones incurred were insignificant and we did not owe any royalties.

Note 9—Shareholders' Deficit

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. For the six months ended June 30, 2018, we received proceeds of \$2.9 million upon the exercise of stock options and warrants which resulted in the issuance of 286,829 shares of common stock.

Warrants

In connection with the April 2018 amendment to the CRG Loan, we issued warrants to purchase up to 200,000 shares of our common stock with an exercise price of \$23.00 per share and total fair value of \$1.4 million. The warrants have a five-year term and remain outstanding as of June 30, 2019.

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, 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>

	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
	(In thousands)			
Balance January 1, 2018	\$ 482	\$ 520,072	\$ (523,368)	\$ (2,814)
Exercise of stock options	1	686	—	687
Stock-based compensation expense	—	2,966	—	2,966
Net loss	—	—	(30,054)	(30,054)
Balance March 31, 2018	483	523,724	(553,422)	(29,215)
Warrants issued	—	1,424	—	1,424
Exercise of stock options	2	2,188	—	2,190
Stock-based compensation expense	—	3,000	—	3,000
Net loss	—	—	(33,696)	(33,696)
Balance June 30, 2018	<u>\$ 485</u>	<u>\$ 530,336</u>	<u>\$ (587,118)</u>	<u>\$ (56,297)</u>

Note 10—Stock-Based Compensation

Stock-based compensation expense includes the amortization of stock options granted to employees and non-employees and has been reported in our Condensed Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Research and development	\$ 1,646	\$ 1,185	\$ 3,140	\$ 2,385
Selling, general and administrative	1,952	1,815	3,833	3,581
Total	<u>\$ 3,598</u>	<u>\$ 3,000</u>	<u>\$ 6,973</u>	<u>\$ 5,966</u>

The fair value of each option grant to employees, directors and non-employees 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,		Six Months Ended June 30,	
	2019	2018	2019	2018
Estimated weighted-average fair value	\$ 12.06	\$ 9.78	\$ 9.76	\$ 9.77
Weighted-average assumptions:				
Expected volatility	80 %	77 %	81 %	77 %
Expected term, in years	5.9	6.0	6.0	6.0
Risk-free interest rate	2.32 %	2.67 %	2.46 %	2.66 %
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, 2018	10,313,138	\$ 11.22		
Granted	1,808,055	13.93		
Exercised	(184,365)	9.26		
Forfeited	(135,869)	14.31		
Balance at June 30, 2019	11,800,959	\$ 11.63	6.46	\$ 51,916
Vested and expected to vest at June 30, 2019	11,397,006	\$ 11.54	6.37	\$ 51,033
Exercisable at June 30, 2019	8,079,645	\$ 10.52	5.31	\$ 43,591

At June 30, 2019, there were 3,721,314 unvested options outstanding that will vest over a weighted-average period of 2.8 years and 5,420,024 shares were available to grant which includes shares registered in June 2019 under the Omeros Corporation 2017 Omnibus Incentive Compensation Plan, as amended and restated effective June 7, 2019. The total estimated compensation expense yet to be recognized on outstanding options is \$30.3 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 to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative pain. In our pipeline we have clinical-stage development programs focused on complement-associated thrombotic microangiopathies, complement-mediated glomerulonephropathies, and addictive and compulsive disorders. In addition, we have a diverse group of preclinical programs and two platforms: one capable of unlocking new G protein-coupled receptor (GPCR) drug targets and the other used to generate antibodies. For OMIDRIA and each of our product candidates and our programs, we have retained control of all commercial rights.

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 of 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 intraocular lens 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. These procedures are typically performed to replace a lens opacified by a cataract and/or to correct a refractive error. 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 ambulatory surgery centers (ASCs) and hospitals. The Centers for Medicare & Medicaid Services (CMS), 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, the Consolidated Appropriations Act of 2018 (the Appropriations Act) was signed into law. The Appropriations Act included a provision by which 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 until October 1, 2020.

We continue to pursue permanent separate reimbursement for OMIDRIA. In the 2019 final rule for CMS' outpatient prospective payment system (OPPS), CMS indicated that, in the ASC setting, it will separately pay for certain non-opioid drugs used during surgery that have an FDA-approved indication for postoperative pain relief and are currently packaged with the procedure in calendar year 2019. In its OPPS proposed rule for 2020, CMS indicates an intention to continue its policy of paying separately for non-opioid drugs indicated for postoperative pain relief when

used during surgery. The 2020 proposed rule notes that non-opioid drugs that are indicated for reduction of post-operative pain may warrant separate payment if there is evidence to show that such drugs help to deter or avoid prescription opioid use and addiction and that packaged payment presents a demonstrated barrier to access for such drugs. Although OMIDRIA is not specifically named in the proposed rule, we believe that we will soon have adequate evidence to demonstrate that OMIDRIA meets these criteria and that the drug warrants separate payment after the scheduled expiration of pass-through reimbursement on September 30, 2020. We are continuing to confirm this belief and to pursue other avenues of permanent separate payment or similar reimbursement for OMIDRIA beyond September 30, 2020; however, we cannot provide assurance that these efforts will be successful. For more information regarding OMIDRIA reimbursement, see “Results of Operations” below.

We also continue to pursue expansion of reimbursement for OMIDRIA by Medicare Advantage and other third-party payers. CMS recently assigned a permanent product-specific Healthcare Common Procedure Coding System (HCPCS) J-code for OMIDRIA, which will become effective October 1, 2019. J-codes are reimbursement codes used by commercial insurance plans, Medicare, Medicare Advantage, and other government payers for drugs like OMIDRIA that are administered by a physician. Claims submission and payment are standardized with a J-code, which facilitates and streamlines billing and reimbursement across payer categories. We expect many of the commercial insurers that previously would not reimburse providers for OMIDRIA under the drug’s current temporary HCPCS C-code to begin providing reimbursement for OMIDRIA under the newly assigned permanent J-code.

In July 2018, we reported that OMIDRIA had been placed on the market in the EU, on a limited basis, which maintained the ongoing validity of the European marketing authorization for OMIDRIA. Decisions about price and reimbursement for OMIDRIA are made on a country-by-country basis and may be required before marketing may occur in a particular country. At this time, we do not expect to see significant sales of OMIDRIA in any countries within the EEA or other international territories.

Clinical Development Programs

Our clinical stage development programs include:

- *MASP-2 - narsoplimab (OMS721) - Lectin Pathway Disorders*. Narsoplimab, also referred to as OMS721, is our lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2) is 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.

Phase 3 clinical programs are underway for narsoplimab in: hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA); Immunoglobulin A (IgA) nephropathy; and atypical hemolytic uremic syndrome (aHUS). In addition, we have an ongoing Phase 2 clinical trial evaluating narsoplimab in renal diseases, currently focused on patients with IgA nephropathy.

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.

Hematopoietic stem cell transplant-associated TMA is a significant, costly and often lethal complication of stem cell transplants. HSCT-TMA is a systemic, multifactorial condition caused by endothelial cell damage induced by infection, graft-versus-host disease, and therapies used as part of stem cell transplantation. There is growing recognition within the stem-cell transplant community of the high incidence and severity of this transplant complication. Historically, the literature-based incidence of HSCT-TMA has been varied, with some smaller centers and national registries reporting low numbers of cases while major research institutions reported incidences in the range of 15-25 percent. More recently, however, as TMA has become better understood and identified, its reported occurrence has been approximately 40 percent in patients undergoing allogeneic hematopoietic stem cell transplants in centers that screen for the disease. The condition is associated with an increased mortality rate and, in those patients who survive, it often causes chronic kidney damage. There are currently no approved products for the treatment or prevention of HSCT-TMA.

Previously announced results from patients with HSCT-TMA in our ongoing Phase 3 program demonstrated a greater than 16-fold increase in median overall survival and a greater than 5-fold increase in 100-day survival in patients treated with narsoplimab compared to a literature-based control. In addition to and consistent with the survival data reported, assessments of platelet count, lactate dehydrogenase, and haptoglobin - all markers of TMA activity - demonstrated clinically meaningful and statistically significant improvements in the HSCT-TMA patients treated with narsoplimab. Improvement in transfusion requirements and organ function were also observed. No safety concerns were identified. Adverse events and causes of death were consistent with the patients' underlying diseases.

Based on communications with the FDA and the EMA regarding expectations for our marketing applications (BLA and MAA), we plan to submit for regulatory approval of narsoplimab for HSCT-TMA with data from patients already enrolled in the ongoing HSCT-TMA clinical trial and from HSCT-TMA patients previously or currently being treated with narsoplimab under compassionate use protocols. We have also agreed with the FDA on the primary endpoint criteria to be used for approval. The response-based primary endpoint for HSCT-TMA requires a showing of both a beneficial effect on the underlying HSCT-TMA disease process and a meaningful improvement in patients' clinical status. The endpoint includes laboratory measures and markers of organ function as well as platelet and red blood cell transfusion burden. We are collecting the additional data needed for our marketing applications from the medical records of patients already treated with narsoplimab in our HSCT-TMA clinical trial or under a compassionate use protocol. As part of a successful pre-BLA meeting directed to chemistry, manufacturing and controls (CMC), we have also discussed with FDA the CMC requirements for the narsoplimab BLA for HSCT-TMA and are confident in our ability to meet them. We have submitted to FDA our proposed schedule for rolling BLA submission. The nonclinical sections of the BLA are expected to comprise the first module of the rolling BLA submission.

In Europe, we have already applied for, and EMA confirmed, eligibility to EMA's centralized review procedure, which allows submission of a single MAA that, if approved, authorizes the product to be marketed in all EU member states and EEA countries rather than requiring separate national approvals. We are also finalizing our Pediatric Investigational Plan in Europe, which is a prerequisite for submission of the MAA. The EMA has appointed rapporteurs to work with us through the MAA submission process, and meetings with our rapporteurs have already begun. The rapporteurs are members of the EMA's Committee for Human Medicinal Products (CHMP) and will jointly coordinate CHMP's evaluation of our MAA for narsoplimab for the treatment of HSCT-TMA. We are engaged with the appointed rapporteurs regarding the path to European approval of narsoplimab for HSCT-TMA and intend to harmonize the contents of the BLA and 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 (RAS) 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 - OMS527. In our phosphodiesterase 7 (PDE7) program, we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders. Dosing has been completed in 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. The double-blind, randomized, placebo-controlled trial evaluated six cohorts of eight volunteers in the single-ascending-dose portion of the trial, including a cohort to assess whether pharmacokinetics is affected by food, and three cohorts of 12 volunteers in the multiple-ascending-dose portion. The compound was generally well tolerated with no significant adverse events being reported. The pharmacokinetic data support once-daily dosing, with or without food. We plan to conduct a Phase 2a study targeting nicotine addiction.

Preclinical Development Programs and Platforms

Our preclinical programs and platforms include:

- MASP-3 - OMS906 - Alternative Pathway Disorders. As part of our complement target 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). 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, and 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 program has generated positive data in a well-established animal model associated with PNH

including in non-human primates. The program has also generated positive data in a well-established animal model of arthritis. In preparation for clinical trials, the manufacturing scale-up process is underway for a MASP-3 inhibitor antibody. The initial clinical focus in this program is PNH. Nonclinical human-dose-enabling studies are planned for this year and clinical trials are targeted to begin in the first half of 2020.

- 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. As part of lifecycle planning for narsoplimab we are developing small-molecule inhibitors of MASP-2 designed for oral administration, as well as a long-acting second-generation antibody against MASP-2 designed for subcutaneous administration. Both of these development programs are targeted for clinical entry in mid-2021. Development efforts are also directed to small-molecule inhibitors of MASP-3 and bispecific inhibitors of MASP-2/-3.
- GPCR Platform and Programs.*** 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 are conducting *in vitro* and *in vivo* preclinical efficacy studies and optimizing compounds for a number of targets. One of our priorities in this program is GPR174. In *ex vivo* human studies, our small-molecule inhibitors targeting GPR174 upregulate the production of cytokines (e.g., IL-2, interferon- γ), block multiple checkpoints (e.g., PDL-1, CTLA-4, LAG-3) and tumor promoters (e.g., amphiregulin), 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 solid and liquid tumors. 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

For the three months ended June 30, 2019 and 2018, we recognized net losses of \$14.5 million and \$33.7 million, respectively, and our OMIDRIA revenues were \$26.8 million and \$1.7 million, respectively. 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. Separate reimbursement payment for OMIDRIA was restored effective October 1, 2018 through September 30, 2020 as a result of securing a two-year extension of pass-through reimbursement status for use of OMIDRIA during procedures performed on Medicare Part B fee-for-service patients. See “Commercial Product - OMIDRIA” earlier in this section for additional details regarding the pass-through reimbursement status for OMIDRIA.



* Fiscal quarters without pass-through reimbursement.

We expect our net losses will continue until 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.

As of June 30, 2019, we had \$31.8 million in cash and cash equivalents and short-term investments available for general corporate use and \$28.5 million in accounts receivable, 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,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Product sales, net	\$ 26,753	\$ 1,655	\$ 48,532	\$ 3,244

During the three and six months ended June 30, 2019, OMIDRIA revenue was \$26.8 million and \$48.5 million as compared to \$1.7 million and \$3.2 million for the three and six months ended June 30, 2018. The increase in revenue during the three and six months ended June 30, 2019 compared to the same period in prior year was due to significantly increased demand for OMIDRIA by ASCs and hospitals following the reinstatement of transitional pass-through reimbursement status for OMIDRIA on October 1, 2018. As compared to the first quarter of 2019, OMIDRIA revenue for the second quarter of 2019 increased \$5.0 million, or 22.8%, from \$21.8 million due to continuous increased demand for OMIDRIA.

We anticipate that OMIDRIA product sales, net, will continue to increase during 2019; however, we are unable to predict with precision the magnitude of those increases at the current time due to the recent reinstatement of pass-through status for OMIDRIA. In addition, there is uncertainty regarding the extent to which the recent issuance by CMS of a product-specific J-code for OMIDRIA will positively impact sales of OMIDRIA and uncertainty regarding what impact, if any, the issuance by CMS of the OPPS final rule for 2020 may have on sales of OMIDRIA.

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, 2019 was 28.2% and 27.7% of gross OMIDRIA product sales, respectively. This compares to 20.4% and 24.8% for the three and six months ended June 30, 2018, respectively. The primary reason for the increase in gross-to-net deductions as a percentage of sales is due to increased chargebacks and rebates under our volume-purchase discount program. We expect our gross-to net deductions will increase slightly from the three and six months ended June 30, 2019 during the remainder of 2019.

A summary of our gross-to-net related accruals for the six months ended June 30, 2019 is as follows:

	Chargebacks and Rebates	Distribution Fees and Product Return Allowances	Total
		(In thousands)	
Balance as of December 31, 2018	\$ 7,015	\$ 1,485	\$ 8,500
Provisions	16,126	2,430	18,556
Payments	(13,904)	(2,241)	(16,145)
Balance as of June 30, 2019	\$ 9,237	\$ 1,674	\$ 10,911

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 beginning in April 2019, an off-invoice discount to our ASC and hospital customers. We also record a provision for estimated rebates 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.

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 and manufacturing scale-up costs; 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, contract research organizations (CROs), clinical trial sites, collaborators, consultants, and lab supplies. 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,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Direct external expenses:				
Clinical research and development:				
MASP-2 Program - OMS721 (narsoplimab)	\$ 5,058	\$ 8,315	\$ 19,495	\$ 16,243
OMIDRIA - Ophthalmology	379	675	1,087	1,284
PDE7 - OMS527	603	—	1,179	—
Other clinical programs	145	450	270	662
Total clinical research and development	6,185	9,440	22,031	18,189
Preclinical research and development	1,957	2,807	3,347	4,438
Total direct external expenses	8,142	12,247	25,378	22,627
Internal, overhead and other expenses	9,320	5,980	16,845	12,539
Stock-based compensation expense	1,646	1,185	3,140	2,385
Total research and development expenses	<u>\$ 19,108</u>	<u>\$ 19,412</u>	<u>\$ 45,363</u>	<u>\$ 37,551</u>

Direct external expenses decreased for the three months and increased for the six months ended June 30, 2019, compared to the same periods in 2018, respectively. The decrease in the three-month period and the increase in the six-

month period are due primarily to the timing of third-party manufacturing scale up costs as we continue to increase our production capacity to meet anticipated clinical and commercial requirements in our narsoplimab program, and the inclusion of clinical costs associated with the initiation of a Phase 1 clinical trial for OMS527, our PDE7 program for addiction and compulsive disorders. The decline in direct external expenses related to our preclinical development expense for the three and six months ended June 30, 2019 compared to the same periods in 2018 reflects the advancement of OMS527 into clinical research and development in July 2018 while maintaining a similar level of expenditures related to our preclinical programs.

The increases in internal, overhead and other expenses for the three and six months ended June 30, 2019 compared to the prior year periods are primarily due to additional employee-related costs to support our increased research and development activities.

The increase in stock-based compensation expense for the three and six months ended June 30, 2019 compared to the prior year periods is due primarily to increases in the number of shares granted as our research and development staff has grown, as well as the Black-Scholes value per share being greater for annual performance grants made in 2019 compared to prior years.

The majority of our research and development expenses for the second half of 2019 are anticipated to be related to our narsoplimab program. We expect research and development costs to increase throughout 2019 as we continue our Phase 3 clinical programs for narsoplimab and incur manufacturing scale-up costs and other expenses as we continue preparations for the anticipated submission of marketing applications for narsoplimab in HSCT-TMA and the potential commercialization of narsoplimab in HSCT-TMA in the U.S. and Europe. However, the timing of research and development expenses on a quarterly basis will be highly variable depending on the timing of manufacturing and clinical trial activities and regulatory review of our product candidates and programs.

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. 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Selling, general and administrative expenses, excluding stock-based compensation expense	\$ 14,976	\$ 10,929	\$ 27,727	\$ 20,097
Stock-based compensation expense	1,952	1,815	3,833	3,581
Total selling, general and administrative expenses	<u>\$ 16,928</u>	<u>\$ 12,744</u>	<u>\$ 31,560</u>	<u>\$ 23,678</u>

The increase in selling, general and administrative expenses during the three and six months ended June 30, 2019 compared to the same periods in 2018 was primarily due to increased pre-commercialization activities for narsoplimab, sales and marketing costs related to the re-introduction of OMIDRIA, fees related to patent applications, consulting and professional service fees, and employee-related costs.

We expect that our selling, general and administrative expenses will increase slightly in the remaining quarters of 2019 compared to current levels, primarily due to increased pre-commercialization activities for narsoplimab.

Interest Expense

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Interest expense	\$ 5,530	\$ 3,676	\$ 11,130	\$ 6,502

The increase in interest expense during the three and six months ended June 30, 2019 compared to the same periods in the prior year was primarily due to the issuance, in November 2018, of \$210.0 million aggregate principal amount of our 6.25% Convertible Senior Notes due 2023 (the Convertible Notes). Non-cash interest expense for the three and six months ended June 30, 2019 was \$2.2 million and \$4.4 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 10K for the year ended December 31, 2018](#).

Financial Condition - Liquidity and Capital Resources

For the six months ended June 30, 2019, we generated net losses of \$38.8 million and incurred negative cash flows from operations of \$29.5 million compared to \$63.8 million and \$42.2 million, respectively, for the six months ended June 30, 2018. As of June 30, 2019, we had \$31.8 million in cash, cash equivalents and short-term investments available for general corporate use that are held principally in money-market accounts. Our accounts receivable balance at June 30, 2019 was \$28.5 million and we had \$40.7 million of current liabilities.

In August 2019, we entered into a Loan and Security Agreement with Silicon Valley Bank (the SVB Loan Agreement), which provides for a \$50 million revolving line of credit facility. We may draw at our discretion, on a revolving basis, up to the lesser of \$50 million and a borrowing base of 85% of eligible accounts receivable, less certain reserves. The SVB Loan Agreement does not encumber any of our intellectual property or development program inventories; our obligations under the SVB Loan Agreement are secured by our remaining assets.

As described earlier in this section under “Commercial Product — OMIDRIA”, pass-through status for OMIDRIA allows for separate reimbursement payment (*i.e.*, outside the packaged procedural payment) to ASCs and hospitals using OMIDRIA in procedures involving patients covered by Medicare Part B. OMIDRIA has been granted pass-through reimbursement through September 30, 2020.

We continue to advance a series of clinical and preclinical programs (including three programs currently in Phase 3). We believe OMIDRIA sales will continue to grow throughout the remainder of 2019 and into 2020. While we believe that OMIDRIA will obtain permanent separate payment beyond the scheduled expiration of pass-through reimbursement on September 30, 2020, we cannot at this time predict with precision the extent or duration of growth in OMIDRIA revenues in 2019 and 2020. As a result, despite our record OMIDRIA sales, meaningful growth in OMIDRIA sales in the second half of 2019 and 2020 are not included in the determination regarding our prospects as a going concern. Similarly, we are unable to include in the determination amounts available under our revolving 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. 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 8, 2020 and, therefore, to continue as a going concern.

We plan to continue to fund a portion of our operations through proceeds from sales of OMIDRIA. 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, and/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, and/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.

Cash Flow Data

	Six Months Ended	
	June 30,	
	2019	2018
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	\$ (29,537)	\$ (42,206)
Investing activities	\$ 26,499	\$ (5,552)
Financing activities	\$ 1,163	\$ 47,247

Operating Activities. Net cash used in operating activities for the six months ended June 30, 2019 decreased by \$12.7 million as compared to the same period in 2018. The net decrease in cash used in operating activities in the current period compared to the prior year is due to a \$25.0 million decrease in our net loss, a \$4.1 million increase in funds provided by increased accounts payable and accrued expense, and a \$2.9 million increase in funds provided through a decrease in advance payments. These improvements to our cash used in operating activities were partially offset by a \$21.3 million decrease in funds provided from the collection of accounts receivable due to increased OMIDRIA sales, and a \$1.3 million increase in funds used to acquire OMIDRIA inventory.

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, 2019 was \$26.5 million, an increase of approximately \$32.1 million from the \$5.6 million net cash used in investing activities for the same period in 2018. During the six months ended June 30, 2019 compared to the same period in 2018, the net change in our investments sold compared to purchased decreased by \$31.9 million. These net proceeds provided cash to fund our operations.

Financing Activities. Net cash provided by financing activities during the six months ended June 30, 2019 was \$1.2 million, a decrease of \$46.1 million compared to the same period in 2018. The decrease in net cash provided by financing activities for the six months ended June 30, 2019 compared to the prior year was primarily due to \$44.6 million in net proceeds from borrowing under our former term loan agreement with CRG Servicing LLC in May 2018. We did not have a similar borrowing during the 2019 period.

Contractual Obligations and Commitments

Our future minimum contractual commitments and obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2018. Other than the following, our future minimum contractual obligations and commitments have not changed materially from the amounts previously reported.

Goods & Services

We have certain non-cancelable obligations under various other agreements for the acquisition of goods and services associated with the manufacturing of our product candidates that contain firm commitments. As of June 30, 2019, our aggregate firm commitments are \$20.4 million.

We may also 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.

Lease Agreements

We have operating leases related to our office and laboratory space in The Omeros Building. The initial term of the leases is through November 2027 and we have two options to extend the lease term, each by five years. We have finance leases for certain laboratory and office equipment that have lease terms expiring through December 2023. On January 1, 2019, we adopted Topic 842. The adoption did not change our contractual obligations related to lease agreements. See Part I, Item 1, Note 7 - "Lease Liabilities" for the maturities of our lease liabilities as of June 30, 2019.

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, 2018, except for the adoption ASU 2016-02, *Leases*. See Part I, Item 1, Note 1 - "Organization and Significant Accounting Policies" and Note 7 - "Lease Liabilities" in this Form 10-Q for additional information about our adoption of ASU 2016-02, *Leases*.

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 and notes payable. 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, 2019, we had cash, cash equivalents and short-term investments of \$31.8 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, 2019. 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, 2019, 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, 2018, as filed with the SEC on March 1, 2019. In assessing the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2018, 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.

There has not been a material change to the risk factors as set forth in our Annual Report on Form 10-K for the year ended December 31, 2018.

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

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
10.1	Seventh Amendment to Lease, dated April 15, 2019, between Omeros Corporation and BMR-201 Elliott Avenue LLC
31.1	Certification of Principal Executive Officer Pursuant to Rule 1314(a) or Rule 15d14(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 1314(a) or Rule 15d14(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 Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104.1	Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101)

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 8, 2019

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

Dated: August 8, 2019

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

SEVENTH AMENDMENT TO LEASE

THIS SEVENTH AMENDMENT TO LEASE (this "Amendment") is entered into as of this 15th day of April, 2019 (the "Effective Date"), by and between BMR-201 ELLIOTT AVENUE LLC, a Delaware limited liability company ("Landlord"), and OMEROS CORPORATION, a Washington corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant are parties to that certain Lease dated as of January 27, 2012 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of November 5, 2012, that certain Second Amendment to Lease dated as of November 16, 2012, that certain Third Amendment to Lease dated as of October 16, 2013, that certain Fourth Amendment to Lease dated as of September 8, 2015, that certain Fifth Amendment to Lease dated as of September 1, 2016, and that certain Sixth Amendment dated as of October 18, 2018 (the "Sixth Amendment") (collectively, and as the same may have been further amended, amended and restated, supplemented or modified from time to time, the "Existing Lease"), whereby Tenant leases certain premises (the "Existing Premises") from Landlord at 201 Elliott Avenue West in Seattle, Washington (the "Building");

B. WHEREAS, Landlord and Tenant desire to expand the Existing Premises to include that certain additional space containing approximately six hundred eighteen (618) square feet of Rentable Area and located on the first (1st) floor of the Building (as more particularly described on Exhibit A attached hereto, the "First Floor Additional Premises"); and

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

AGREEMENT

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

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

2. First Floor Additional Premises. Effective as of the First Floor Additional Premises Commencement Date (as defined below), Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, the First Floor Additional Premises for use by Tenant in accordance with the Permitted Use and in accordance with all other terms and conditions of the Lease, except to the extent inconsistent with the provisions of this Amendment. From and after the First Floor Additional Premises Commencement Date, the term "Premises" as used in the Lease shall include the First Floor Additional Premises.

3. First Floor Additional Premises Term. The Term of the Lease with respect to the First Floor Additional Premises (as the same may be earlier terminated in accordance with the Lease, the “First Floor Additional Premises Term”) shall commence on the Effective Date (the “First Floor Additional Premises Commencement Date”) and remain in effect until March 31, 2020, at which time the First Floor Additional Premises Term shall thereafter be coterminous with the Term for the Existing Premises, such that the Term with respect to the entire Premises (including both the Existing Premises and the First Floor Additional Premises) shall expire on the Term Expiration Date.

4. Condition of First Floor Additional Premises. Tenant acknowledges that (a) it is familiar with the condition of the First Floor Additional Premises and agrees to take the same in its condition “as is” as of the First Floor Additional Premises Commencement Date, (b) neither Landlord nor any agent of Landlord has made (and neither Landlord nor any agent of Landlord hereby makes) any representation or warranty of any kind whatsoever, express or implied, regarding the First Floor Additional Premises, including (without limitation) any representation or warranty with respect to the condition of First Floor Additional Premises or with respect to the suitability of the First Floor Additional Premises for the conduct of Tenant’s business and (c) Landlord shall have no obligation to alter, repair or otherwise prepare the First Floor Additional Premises for Tenant’s occupancy or to pay for any improvements to the First Floor Additional Premises.

5. First Floor Additional Premises Base Rent and Additional Rent. Commencing as of the First Floor Additional Premises Commencement Date, Base Rent for the First Floor Additional Premises shall equal Thirty-Five Dollars (\$35.00) per square foot of Rentable Area per year and shall be subject to an annual upward adjustment of two point three percent (2.3%) of the then-current Base Rent (with the first such adjustment becoming effective commencing on November 16, 2019, and subsequent adjustments becoming effective on every successive annual anniversary of November 16 for so long as the Lease continues in effect). Commencing as of the First Floor Additional Premises Commencement Date, Tenant shall pay to Landlord Additional Rent (as defined in the Lease) with respect to the First Floor Additional Premises.

6. First Floor Additional Premises Base Rent Abatement. Tenant’s obligations with respect to Base Rent as to the First Floor Additional Premises payable by Tenant pursuant to Section 5 shall be subject to abatement for the first one (1) month of the First Floor Additional Premises Term (the “First Floor Additional Premises Base Rent Abatement”); provided, however, that Tenant shall not be entitled to any portion of the First Floor Additional Premises Base Rent Abatement accruing during a period of time in which Tenant is in Default under the Lease. Upon the occurrence of a Default, Tenant shall immediately be obligated to commence paying Base Rent for the First Floor Additional Premises in full until such time that the Default has been cured. For the avoidance of doubt, the time period for which the First Floor Additional Premises Base Rent Abatement applies shall not be extended as a result of any Default period during which Tenant is not entitled to such First Floor Additional Premises Base Rent Abatement. Tenant acknowledges and agrees that the First Floor Additional Premises Base Rent Abatement has been granted to Tenant as additional consideration for entering into this Amendment and for agreeing to pay the Rent and perform all of the obligations of Tenant under the Lease. The First Floor Additional Premises Base Rent Abatement shall not work to abate or reduce Tenant’s obligations under the Lease with respect to Additional Rent (including, without limitation, Tenant’s obligations with respect to Operating Expenses and the Property Management Fee). For avoidance of doubt, for the first one (1) month of the First Floor Additional Premises Term, the Property Management Fee with respect to the First Floor Additional Premises shall be calculated as if Tenant were paying full Base Rent for the First Floor Additional Premises without taking into account the First Floor Additional Premises Base Rent Abatement.

7. First Floor Additional Premises Pro Rata Share. Tenant's Pro Rata Share of the Project with respect to the First Floor Additional Premises shall be zero and forty-one hundredths percent (0.41%). Commencing as of the First Floor Additional Premises Commencement Date, Tenant's Pro Rata Share of the Project shall be increased to include such amount.

8. First Floor Additional Premises Permitted Use. Notwithstanding anything in the Existing Lease to the contrary, the Permitted Use with respect to the First Floor Additional Premises shall be office use in conformity with all Applicable Laws.

9. Build-to-Suit Option. The parties acknowledge and agree that in the event that Landlord and Tenant enter into a build-to-suit lease pursuant to Section 47 of the Original Lease, then (a) any resulting termination of the Existing Lease in accordance therewith shall also terminate Tenant's lease of the First Floor Additional Premises under this Amendment, and (b) there shall be no termination penalty or charge for the termination of Tenant's lease of the First Floor Additional Premises, and no termination costs related to such termination shall be factored into the economics of the new build-to-suit lease.

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

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

12. Notices. Tenant confirms that, notwithstanding anything in the Lease to the contrary, notices delivered to Tenant pursuant to the Lease should be sent to:

Omeros Corporation
201 Elliott Avenue West
Seattle, Washington 98119
Attn: Chief Executive Officer

with a copy to:

Omeros Corporation
201 Elliott Avenue West
Seattle, Washington 98119
Attn: General Counsel

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

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

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

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

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

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

LANDLORD:

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

By: /s/ Marie Lewis
Name: Marie Lewis
Title: Vice President, Legal

TENANT:

OMEROS CORPORATION,
a Washington corporation

By: /s/ Gregory A. Demopulos
Name: Gregory A. Demopulos, M.D.
Title: Chairman & CEO

EXHIBIT A

ADDITIONAL FIRST FLOOR PREMISES



**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. Demopulos, 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 8, 2019

/s/ Gregory A. Demopulos
Gregory A. Demopulos, 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 8, 2019

/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, 2019, 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 8, 2019

/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, 2019, 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 8, 2019

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer
