

**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 March 31, 2021
or

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

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

OMEROS CORPORATION

(Exact name of registrant as specified in its charter)

Washington
(State or other jurisdiction of
incorporation or organization)

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

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

98119
(Zip Code)

(206) 676-5000

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

As of May 6, 2021, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 62,328,370.

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:

- whether the U.S. Food and Drug Administration (“FDA”) will approve the BLA for our lead MASP-2 inhibitor, narsoplimab in hematopoietic stem cell transplant-associated thrombotic microangiopathy (“HSCT-TMA”);
 - our expectations regarding clinical plans and anticipated or potential paths to regulatory approval of narsoplimab by FDA and/or the European Medicines Agency (“EMA”) in HSCT-TMA, immunoglobulin A nephropathy, atypical hemolytic uremic syndrome and/or COVID-19;
 - whether and when a marketing authorization application may be filed with the EMA for narsoplimab in any indication, and whether the EMA will grant approval for narsoplimab in any indication;
 - our plans for the commercial launch of narsoplimab following any regulatory approval and our estimates and expectations regarding coverage and/or reimbursement for any approved products;
 - our estimates regarding how long our existing cash, cash equivalents, short-term investments and revenues will be sufficient to fund our anticipated operating expenses, capital expenditures and debt service obligations;
 - our expectations relating to demand for OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% from wholesalers, ambulatory surgery centers and/or hospitals, and our expectations regarding OMIDRIA product sales;
 - the severity and duration of the impact of the COVID-19 pandemic on our business, operations, clinical programs and financial results;
 - our expectations related to separate payment for OMIDRIA from the Centers for Medicare & Medicaid Services (“CMS”) and CMS’ separate payment policy for non-opioid pain management surgical drugs, and our expectations regarding reimbursement coverage for OMIDRIA by commercial and government payers;
 - our plans for marketing and distribution of OMIDRIA and our estimates of OMIDRIA chargebacks and rebates, distribution fees and product returns;
 - our expectations regarding the clinical, therapeutic and/or 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 narsoplimab, and for our other investigational candidates, including OMS527 and OMS906;
 - our plans and expectations regarding development of narsoplimab for the treatment of critically ill COVID-19 patients, including statements regarding the therapeutic potential of narsoplimab for the treatment of COVID-19, discussions with government agencies regarding narsoplimab for the treatment of COVID-19, expectations for the treatment of additional COVID-19 patients in clinical trials or other settings and our expectations for receiving any regulatory approval or authorization from FDA or other regulatory body for narsoplimab in the treatment of COVID-19 patients;
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[Table of Contents](#)

- with respect to our narsoplimab clinical programs, our expectations regarding: whether enrollment in any ongoing or planned clinical trial will proceed as expected; whether we can capitalize on the financial and regulatory incentives provided by orphan drug designations granted by FDA, the European Commission, or EMA; and whether we can capitalize on the regulatory incentives provided by fast-track or breakthrough therapy designations granted by FDA;
- our expectation that our contract manufacturers will reliably meet our requirements for commercial supply of OMIDRIA and narsoplimab (if approved) and to meet our supply requirements of our clinical and development stage product candidates;
- 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 MARCH 31, 2021

INDEX

	<u>Page</u>
<u>Part I — Financial Information</u>	5
<u>Item 1.</u> <u>Financial Statements (unaudited)</u>	5
<u>Condensed Consolidated Balance Sheets</u>	5
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss</u>	6
<u>Condensed Consolidated Statements of Cash Flows</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2.</u> <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	19
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	30
<u>Item 4.</u> <u>Controls and Procedures</u>	30
<u>Part II — Other Information</u>	31
<u>Item 1.</u> <u>Legal Proceedings</u>	31
<u>Item 1A.</u> <u>Risk Factors</u>	31
<u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	31
<u>Item 6.</u> <u>Exhibits</u>	31
<u>Signatures</u>	33

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

OMEROS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(unaudited)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,028	\$ 10,501
Short-term investments	91,455	124,452
Receivables, net	24,826	3,841
Inventory	1,191	1,355
Prepaid expense and other assets	5,982	11,136
Total current assets	132,482	151,285
Property and equipment, net	2,173	2,551
Right of use assets	24,994	25,526
Restricted investments	1,054	1,055
Advanced payments, non-current	741	625
Total assets	\$ 161,444	\$ 181,042
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	\$ 11,499	\$ 4,199
Accrued expenses	28,132	28,755
Current portion of lease liabilities	3,803	3,782
Total current liabilities	43,434	36,736
Lease liabilities, non-current	27,806	28,770
Unsecured convertible senior notes, net	312,159	236,288
Commitments and contingencies (Note 9)		
Shareholders' deficit:		
Preferred stock, par value \$0.01 per share, 20,000,000 shares authorized; none issued and outstanding at March 31, 2021 and December 31, 2020.	—	—
Common stock, par value \$0.01 per share, 150,000,000 shares authorized at March 31, 2021 and December 31, 2020; 62,252,012 and 61,671,231 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively.	622	616
Additional paid-in capital	689,882	751,304
Accumulated deficit	(912,459)	(872,672)
Total shareholders' deficit	(221,955)	(120,752)
Total liabilities and shareholders' deficit	\$ 161,444	\$ 181,042

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	
	March 31,	
	2021	2020
Product sales, net	\$ 21,061	\$ 23,537
Costs and expenses:		
Cost of product sales	263	267
Research and development	33,358	28,911
Selling, general and administrative	18,052	18,036
Total costs and expenses	<u>51,673</u>	<u>47,214</u>
Loss from operations	(30,612)	(23,677)
Interest expense	(4,897)	(5,903)
Other income	419	549
Net loss	<u>\$ (35,090)</u>	<u>\$ (29,031)</u>
Comprehensive loss	<u>\$ (35,090)</u>	<u>\$ (29,031)</u>
Basic and diluted net loss per share	<u>\$ (0.57)</u>	<u>\$ (0.53)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>61,928,511</u>	<u>54,299,813</u>

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2021	2020
Operating activities:		
Net loss	\$ (35,090)	\$ (29,031)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,271	3,476
Non-cash interest expense	396	2,533
Depreciation and amortization	390	402
Changes in operating assets and liabilities:		
Receivables	(20,985)	11,068
Inventory	164	(64)
Prepaid expenses and other assets	5,038	628
Accounts payable and accrued expenses	6,562	1,847
Net cash used in operating activities	<u>(40,254)</u>	<u>(9,141)</u>
Investing activities:		
Purchases of property and equipment	(12)	(66)
Purchases of investments	(3)	(3,176)
Proceeds from the sale and maturities of investments	33,000	14,018
Net cash provided by investing activities	<u>32,985</u>	<u>10,776</u>
Financing activities:		
Proceeds upon exercise of stock options and warrants	6,333	2,712
At the market offering costs	(241)	—
Payments on finance lease obligations	(296)	(313)
Net cash provided by financing activities	<u>5,796</u>	<u>2,399</u>
Net (decrease) increase in cash and cash equivalents	<u>(1,473)</u>	<u>4,034</u>
Cash and cash equivalents at beginning of period	10,501	3,084
Cash and cash equivalents at end of period	<u>\$ 9,028</u>	<u>\$ 7,118</u>
Supplemental cash flow information		
Cash paid for interest	\$ 5,995	\$ 89
Property acquired under finance lease	\$ —	\$ 22

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Description of Business

Description of Business

We are a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases, disorders of the central nervous system, addiction and immune-related diseases, including cancers. Our first drug product, OMIDRIA[®] (phenylephrine and ketorolac intraocular solution) 1%/0.3%, is marketed in the United States (“U.S.”) for use during cataract surgery or intraocular lens replacement. In December 2020, the Centers for Medicare & Medicaid Services (“CMS”) confirmed that OMIDRIA qualifies for separate payment when used on Medicare Part B patients in ambulatory surgery centers (“ASCs”), effective retroactively as of October 1, 2020. OMIDRIA’s pass through status, which had allowed for separate payment when used on Medicare Part B patients in the ASC or hospital setting, had expired on October 1, 2020.

Our drug candidate narsoplimab is the subject of a biologics license application (“BLA”) under priority review by the U.S. Food and Drug Administration (“FDA”) for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (“HSCT-TMA”). We also have multiple late-stage clinical development programs in our pipeline, which are focused on: complement-mediated disorders, including immunoglobulin A (“IgA”) nephropathy, atypical hemolytic uremic syndrome (“aHUS”) and COVID-19.

Basis of Presentation

Our condensed consolidated financial statements include the financial position and results of operations of Omeros Corporation (“Omeros”) and our wholly owned subsidiaries. All intercompany transactions have been eliminated, and we have determined we operate in one segment. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of March 31, 2021 and December 31, 2020 and for the three months ended March 31, 2021 and 2020 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2020 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, 2020, which was filed with the U.S. Securities and Exchange Commission (“SEC”) on March 1, 2021.

Risks and Uncertainties

The COVID-19 pandemic and the responses to it by various governmental authorities, the medical community and others have had a significant impact on our business. It is not possible to estimate precisely the future impact of COVID-19 on our business, operations or financial results due to the unknown magnitude, duration and outcome of the pandemic.

We have filed with FDA our narsoplimab BLA for HSCT-TMA, which has been granted priority review with an FDA action date of July 17, 2021 under the Prescription Drug User Fee Act. We anticipate, but cannot guarantee, that narsoplimab will receive FDA approval and will launch in the U.S. in 2021. If approved, we cannot fully predict the timing or the magnitude of narsoplimab revenues, but we believe they will be significant. Our sales and marketing

strategies for the launch of narsoplimab for HSCT-TMA include various milestones at which we commit to incremental spending, providing for flexibility in the timing of costs incurred should the approval of narsoplimab be delayed.

We plan to continue to fund our operations for the next twelve months with our cash and investments from sales of OMIDRIA and, if FDA approval is granted, from sales of narsoplimab for HSCT-TMA. In addition, we may utilize funds available under our line of credit, which allows us to borrow up to 85% of our available accounts receivable borrowing base, less certain reserves, or \$50.0 million, whichever is less. We also entered into a sales agreement to sell shares of our common stock, from time to time, up to an aggregate offering amount of \$150.0 million through an “at the market” equity offering program. Should it be necessary or determined to be strategically advantageous, we could pursue debt financings as well as public and private offerings of our equity securities, similar to those we have previously completed, or other strategic transactions, which may include licensing a portion of our existing technology. Should it be necessary to manage our operating expenses, we would reduce our projected cash requirements by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

Use of Estimates

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

Note 2—Significant Accounting Policies

Revenue Recognition

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

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

Inventory

Inventory is stated at the lower of cost or market determined on a specific identification basis in a manner that approximates the first-in, first-out (“FIFO”) method. Costs include amounts related to third-party manufacturing, transportation and internal labor and overhead. Capitalization of costs as inventory begins when regulatory approval of the product candidate is reasonably assured in the U.S. or the European Union (“EU”). We expense inventory costs related to product candidates as research and development expenses prior to receiving regulatory approval in the respective territory. Inventory is reduced to net realizable value for excess and obsolete inventories based on forecasted demand.

Right of Use Assets and Related Lease Liabilities

We record operating leases as right-of-use assets and recognize the related lease liabilities equal to the fair value of the lease payments using our incremental borrowing rate when the implicit rate in the lease agreement is not readily available. We recognize variable lease payments when incurred. Costs associated with operating lease assets are

recognized on a straight-line basis within operating expenses over the term of the lease. We record finance leases as a component of property and equipment and amortize these assets within operating expenses on a straight-line basis to their residual values over the shorter of the term of the underlying lease or the estimated useful life of the equipment. The interest component of a finance lease is included in interest expense and recognized using the effective interest method over the lease term. We account for leases with initial terms of 12 months or less as operating expenses on a straight-line basis over the lease term.

Stock-Based Compensation

Stock-based compensation expense is recognized for all share-based payments based on estimated fair values as of the date of grant. The fair value of our stock options is calculated using the Black-Scholes option-pricing model, which requires judgmental assumptions around volatility, forfeiture rates and expected option term. Compensation expense is recognized over the optionees' requisite service periods, which is generally the vesting period, using the straight-line method. Forfeiture expense is estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates.

Income Taxes

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

Recently Adopted Pronouncements

On January 1, 2021, we adopted Accounting Standard Update ("ASU") 2020-06, *Debt—Debt with Conversion Options* (Subtopic 470-20) and *Derivatives and Hedging—Contracts in Entity's Own Equity* (Subtopic 815-40) on a modified retrospective basis. ASU 2020-06 removes the separate liability and equity accounting for our convertible senior notes. Consequently, we now account for our convertible senior notes wholly as debt. (See "Note 3 – Net Loss Per Share" and "Note 7 – Unsecured Convertible Senior Notes" for further information)

On January 1, 2021, we adopted ASU 2019-12, *Income Taxes* (Topic 740), which is intended to simplify various aspects of the income tax accounting guidance, including elimination of the exception to the incremental approach of intra-period tax allocation when there is a loss from continuing operations and income or gain from other items (for example, other comprehensive income). We adopted the standard on a prospective basis and the impact to our consolidated financial statements for the three months ended March 31, 2021 was immaterial.

Note 3—Net Loss Per Share

Our potentially dilutive securities include potential common shares related to our stock options, warrant and unsecured convertible senior notes. Diluted earnings per share ("Diluted EPS") considers the impact of potentially dilutive securities except in periods in which there is a loss because the inclusion of the potential common shares would have an anti-dilutive effect. Shares issuable under the unsecured convertible notes are calculated using the if-converted method and are excluded from the below table as their impact is anti-dilutive. Diluted EPS excludes the impact of potential common shares related to our stock options in periods in which the option exercise price is greater than the average market price of our common stock for the period.

Potentially dilutive securities excluded from Diluted EPS are as follows:

	Three Months Ended March 31,	
	2021	2020
Outstanding options to purchase common stock	3,453,133	1,659,029
Outstanding warrants to purchase common stock	—	10,901
Total potentially dilutive shares excluded from loss per share	<u>3,453,133</u>	<u>1,669,930</u>

Note 4—Certain Balance Sheet Accounts

Accounts Receivable, net

Accounts receivable, net consist of the following:

	March 31, 2021	December 31, 2020
	(In thousands)	
Trade receivables, net	\$ 24,576	\$ 3,771
Sublease and other receivables	250	70
Total accounts receivables, net	<u>\$ 24,826</u>	<u>\$ 3,841</u>

Trade receivables net of product return and chargeback allowances were \$1.5 million and \$1.2 million as of March 31, 2021 and December 31, 2020, respectively.

Inventory

Inventory consists of the following:

	March 31, 2021	December 31, 2020
	(In thousands)	
Raw materials	\$ 242	\$ 109
Work-in-progress	405	462
Finished goods	544	784
Total inventory	<u>\$ 1,191</u>	<u>\$ 1,355</u>

Property and Equipment, Net

Property and equipment, net consists of the following:

	March 31, 2021	December 31, 2020
	(In thousands)	
Finance leases	\$ 5,690	\$ 5,690
Laboratory equipment	2,910	2,898
Computer equipment	985	985
Office equipment and furniture	625	625
Total cost	<u>10,210</u>	<u>10,198</u>
Less accumulated depreciation and amortization	<u>(8,037)</u>	<u>(7,647)</u>
Total property and equipment, net	<u>\$ 2,173</u>	<u>\$ 2,551</u>

For the three months ended March 31, 2021 and 2020, depreciation and amortization expenses were \$0.4 million.

Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2021	December 31, 2020
	(In thousands)	
Sales rebates, fees and discounts	\$ 6,871	\$ 3,326
Contract research and development	6,146	7,952
Consulting and professional fees	5,002	5,393
Interest payable	3,703	5,205
Employee compensation	3,665	3,948
Clinical trials	2,007	2,121
Other accrued expenses	738	810
Total accrued expenses	<u>\$ 28,132</u>	<u>\$ 28,755</u>

Note 5—Fair-Value Measurements

As of March 31, 2021, and December 31, 2020, 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:

	March 31, 2021			Total
	Level 1	Level 2	Level 3	
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted investments	\$ 1,054	\$ —	\$ —	\$ 1,054
Money-market funds classified as short-term investments	91,455	—	—	91,455
Total	<u>\$ 92,509</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 92,509</u>
	December 31, 2020			Total
	Level 1	Level 2	Level 3	
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted investments	\$ 1,055	\$ —	\$ —	\$ 1,055
Money-market funds classified as short-term investments	124,452	—	—	124,452
Total	<u>\$ 125,507</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 125,507</u>

Cash held in demand deposit accounts of \$9.0 million and \$10.5 million is excluded from our fair-value hierarchy disclosure as of March 31, 2021 and December 31, 2020, respectively. There were no unrealized gains or losses associated with our investments as of March 31, 2021 or December 31, 2020. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets for receivables, accounts payable, other current monetary assets and liabilities approximate fair value.

See “Note 7—Unsecured Convertible Senior Notes” for the carrying amount and estimated fair value of our outstanding convertible senior notes.

Note 6—Line of Credit

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

As of March 31, 2021 and December 31, 2020, no amounts were outstanding under the Line of Credit Agreement.

Note 7—Unsecured Convertible Senior Notes

On January 1, 2021, we early adopted ASU 2020-06 on a modified retrospective basis. ASU 2020-06 removes the separate liability and equity accounting for our outstanding convertible senior notes. Consequently, we now account for our convertible senior notes wholly as debt. Adoption of ASU 2020-06 resulted in a cumulative effect adjustment of \$75.5 million to restore our unsecured convertible notes and additional paid-in capital to the balances without an equity allocation component. The carrying value of the notes are reflective of their face value less unamortized debt issuance costs. Interest expense recognized in future periods will be reduced as a result of accounting for the unsecured convertible notes wholly as a liability measured at amortized cost.

Unsecured convertible senior notes outstanding at March 31, 2021 and December 31, 2020 are as follows:

	Balance as of March 31, 2021		
	2023 Notes	2026 Notes (In thousands)	Total
Principal amount	\$ 95,000	\$ 225,030	\$ 320,030
Unamortized debt issuance costs	(1,749)	(6,122)	(7,871)
Total unsecured convertible senior notes, net	<u>\$ 93,251</u>	<u>\$ 218,908</u>	<u>\$ 312,159</u>
Fair value of outstanding unsecured convertible senior notes (1)	<u>\$ 114,119</u>	<u>\$ 279,431</u>	
Amount by which the unsecured convertible senior notes if-converted value exceeds their principal amount	<u>\$ 19,119</u>	<u>\$ 54,401</u>	

	Balance as of December 31, 2020		
	2023 Notes	2026 Notes (In thousands)	Total
Principal amount	\$ 95,000	\$ 225,030	\$ 320,030
Unamortized discount	(17,101)	(60,544)	(77,645)
Unamortized issuance costs attributable to liability component	(1,481)	(4,616)	(6,097)
Total unsecured convertible senior notes, net	<u>\$ 76,418</u>	<u>\$ 159,870</u>	<u>\$ 236,288</u>
Fair value of outstanding unsecured convertible senior notes (1)	<u>\$ 101,769</u>	<u>\$ 246,779</u>	
Amount by which the unsecured convertible senior notes if-converted value exceeds their principal amount	<u>\$ 6,769</u>	<u>\$ 21,749</u>	
Equity component	\$ 25,854	\$ 63,544	
Unamortized issuance costs	(837)	(1,916)	
Net carrying amount of equity component (2)	<u>\$ 25,017</u>	<u>\$ 61,628</u>	

- (1) The fair value is classified as Level 3 due to the limited trading activity for the unsecured convertible senior notes.
- (2) Included in the Condensed Consolidated Balance Sheet within additional paid-in capital at December 31, 2020. Upon early adoption of ASU 2020-06 on January 1, 2021, amounts were reclassified to unsecured convertible senior notes, net.

2023 Unsecured Convertible Senior Notes

On November 15, 2018, we issued \$210.0 million in aggregate principal amount of our 6.25% convertible senior notes (the “2023 Notes”). The 2023 Notes accrue interest at an annual rate of 6.25% per annum, payable semi-annually in arrears on May 15 and November 15 of each year. The 2023 Notes mature on November 15, 2023 unless earlier purchased, redeemed or converted in accordance with their terms. On August 14, 2020, we issued the 5.25% convertible senior notes (the “2026 Notes”) and used approximately \$125.6 million of the net proceeds to repurchase \$115.0 million principal amount of the 2023 Notes (see “2026 Unsecured Convertible Senior Notes” below).

The 2023 Notes are convertible into cash, shares of our common stock or a combination thereof, as we elect at our sole discretion. The initial conversion rate is 52.0183 shares of our common stock per \$1,000 of note principal (equivalent to an initial conversion price of approximately \$19.22 per share of common stock), subject to adjustment in certain circumstances. To reduce the dilutive impact or potential cash expenditure associated with the conversion of the 2023 Notes, we entered into a capped call transaction (the “2023 Capped Call”), which covers the number of shares of our common stock underlying the 2023 Notes when our common stock is trading between the initial conversion price of \$19.22 per share and \$28.84 per share. In connection with the partial repurchase of the 2023 Notes, we entered into a capped call termination contract to unwind a proportionate amount of the 2023 Capped Call. As of March 31, 2021, approximately 4.9 million shares remained outstanding on the 2023 Capped Call.

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

	Three Months Ended March 31,	
	2021	2020
	(In thousands)	
Contractual interest expense	\$ 1,484	\$ 3,281
Amortization of debt issuance costs	150	202
Amortization of debt discount	—	2,331
Total	<u>\$ 1,634</u>	<u>\$ 5,814</u>

2026 Unsecured Convertible Senior Notes

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

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

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

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

At our sole discretion, we may elect to convert the 2026 Notes into cash, shares of our common stock or a combination thereof at maturity. Subject to the satisfaction of certain conditions, beginning August 15, 2023, we may redeem in whole or in part the 2026 Notes at our option at a cash redemption price equal to the principal amount of the 2026 Notes plus any accrued and unpaid interest.

In order to reduce the dilutive impact or potential cash expenditure associated with the conversion of the 2026 Notes, we entered into capped call transactions (the “2026 Capped Calls”). The 2026 Capped Calls will cover the number of shares of common stock underlying the 2026 Notes when our common stock is trading within the range of approximately \$18.49 and \$26.10. However, should the market price of our common stock exceed the \$26.10 cap, then the conversion of the 2026 Notes would have a dilutive impact or may require a cash expenditure to the extent the market price exceeds the cap price.

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

	Three Months Ended March 31, 2021 (In thousands)
Contractual interest expense	\$ 2,954
Amortization of debt issuance costs	246
Total	\$ 3,200

Future minimum payments for the 2023 and 2026 Notes as of March 31, 2021 are as follows:

	(In thousands)
2021	\$ —
2022	—
2023	95,000
2024	—
2025	—
2026	225,030
Total future minimum payments under the convertible senior notes	<u>\$ 320,030</u>

Note 8—Leases

We have an operating lease for our office and laboratory facilities with an initial term that ends in 2027 with two options to extend the lease term by five years. We carry various finance leases for laboratory equipment.

Supplemental lease information is as follows:

	Three Months Ended	
	2021	2020
	(In thousands)	
Lease cost		
Operating lease cost	\$ 1,583	\$ 1,509
Finance lease cost:		
Amortization	323	357
Interest	63	89
Variable lease cost	813	542
Sublease income	(418)	(293)
Net lease cost	<u>\$ 2,364</u>	<u>\$ 2,204</u>

Cash paid for amounts included in the measurement of lease liabilities is as follows:

	Three Months Ended	
	2021	2020
	(In thousands)	
Cash payments for operating leases	\$ 3,381	\$ 2,136
Cash payments for financing leases	\$ 354	\$ 402

Note 9—Commitments and Contingencies

Contracts

We have various agreements with third parties that would collectively require payment of termination fees if we cancelled work as of March 31, 2021.

Development Milestones and Product Royalties

We have licensed a variety of intellectual property from third parties that we are currently developing or may develop in the future. These licenses may require milestone payments in connection with clinical development or commercial milestones as well as low single to low double-digit royalties on the net income or net sales of the product.

For the three months ended March 31, 2021 and 2020, development milestone expenses were insignificant. We do not owe any royalties on OMIDRIA. Should narsoplimab be approved, we would owe milestone payments to development partners and be obligated to pay low single-digit royalties on net sales of the product.

Note 10—Shareholders’ Deficit

Common Stock and Warrants

On March 1, 2021, we entered into a sales agreement to sell shares of our common stock having an aggregate offering price of up to \$150.0 million, from time to time, through an “at the market” equity offering program. As of March 31, 2021, we have not sold any shares under this program.

During the three months ended March 31, 2021, a cashless exercise was executed for 43,115 warrants, resulting in the issuance of 24,901 shares of our common stock. As of March 31, 2021, 200,000 warrants remained outstanding with an exercise price of \$23.00 per share. The warrants expire on April 12, 2023.

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, 2021	\$ 616	\$ 751,304	\$ (872,672)	\$ (120,752)
Exercise of stock options	6	6,327	—	6,333
At the market offering costs	—	(241)	—	(241)
Cumulative effect of adopting ASU 2020-06	—	(70,779)	(4,697)	(75,476)
Stock-based compensation expense	—	3,271	—	3,271
Net loss	—	—	(35,090)	(35,090)
Balance March 31, 2021	<u>\$ 622</u>	<u>\$ 689,882</u>	<u>\$ (912,459)</u>	<u>\$ (221,955)</u>

	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
	(In thousands)			
Balance January 1, 2020	\$ 542	\$ 625,048	\$ (734,611)	\$ (109,021)
Exercise of stock options	3	2,709	—	2,712
Stock-based compensation expense	—	3,476	—	3,476
Net loss	—	—	(29,031)	(29,031)
Balance March 31, 2020	<u>\$ 545</u>	<u>\$ 631,233</u>	<u>\$ (763,642)</u>	<u>\$ (131,864)</u>

Note 11—Stock-Based Compensation

Stock-based compensation expense is as follows:

	Three Months Ended March 31,	
	2021	2020
	(In thousands)	
Research and development	\$ 1,480	\$ 1,447
Selling, general and administrative	1,791	2,029
Total	<u>\$ 3,271</u>	<u>\$ 3,476</u>

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

	Three Months Ended March 31, 2021
Estimated weighted-average fair value	\$ 13.15
Weighted-average assumptions:	
Expected volatility	81 %
Expected life, in years	6.1
Risk-free interest rate	0.71 %
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, 2020	11,938,528	\$ 11.92		
Granted	244,500	19.09		
Exercised	(555,880)	11.39		
Canceled	(69,603)	15.26		
Balance at March 31, 2021	<u>11,557,545</u>	<u>\$ 12.08</u>	<u>5.9</u>	<u>\$ 67,933</u>
Vested and expected to vest at March 31, 2021	<u>11,223,195</u>	<u>\$ 12.03</u>	<u>5.8</u>	<u>\$ 66,493</u>
Exercisable at March 31, 2021	<u>8,591,292</u>	<u>\$ 11.55</u>	<u>4.9</u>	<u>\$ 54,999</u>

As of March 31, 2021, there were 3.0 million unvested options outstanding that will vest over a weighted-average period of 2.5 years and 3.9 million shares were available to grant. The total estimated compensation expense yet to be recognized on outstanding options is \$22.7 million.

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

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

Overview

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

Our drug product OMIDRIA[®] is marketed in the United States for use during cataract surgery or intraocular lens replacement for adult and pediatric patients. Our drug candidate narsoplimab is the subject of a biologics license application ("BLA") under priority review by the U.S. Food and Drug Administration ("FDA") for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy ("HSCT-TMA"). We also have multiple late-stage clinical development programs in our pipeline, which are focused on complement-mediated disorders, including immunoglobulin A ("IgA") nephropathy, atypical hemolytic uremic syndrome ("aHUS") and COVID-19. We have also initiated a Phase 1 clinical program for our MASP-3 inhibitor OMS906 targeting the alternative pathway of complement and have successfully completed a Phase 1 study in our phosphodiesterase 7 ("PDE7") program focused on addiction. In addition, we have a diverse group of preclinical programs including GPR174, a novel target in immuno-oncology that modulates a new cancer immunity axis that we discovered. Small-molecule and antibody inhibitors of GPR174 are part of our proprietary G protein-coupled receptor ("GPCR") platform through which we control 54 GPCR drug targets and their corresponding compounds. We also have a proprietary-asset-enabled antibody-generating technology. We have retained control of all commercial rights for OMIDRIA and each of our product candidates and programs.

Impact of Global Pandemic

The COVID-19 pandemic and the responses to it by various governmental authorities, the medical community and others continue to have a significant impact on our business. In March 2020, ambulatory surgery centers ("ASCs") and hospitals using OMIDRIA postponed nearly all cataract surgery in response to recommendations from government and medical organizations. As a result, we did not record any sales of OMIDRIA to our wholesalers from March 25 to May 19, 2020. However, by the end of June 2020, the run rate of weekly OMIDRIA sales had recovered to levels approximating those seen prior to the pandemic. It is not possible to estimate precisely the future impact of COVID-19 on our business, operations or financial results due to the unknown magnitude, duration and outcome of the pandemic, especially in light of the severity and transmissibility of virus variants and possible local governmental responses across the U.S.

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

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

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

We sell OMIDRIA primarily through wholesalers which, in turn, sell to 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 from January 1, 2015 through December 31, 2017. Pass-through status allows for separate payment (i.e., outside the packaged payment rate for the surgical procedure) under Medicare Part B. In March 2018, Congress extended pass-through reimbursement status for OMIDRIA through September 30, 2020 when used during procedures performed on Medicare Part B fee-for-service patients. Pass-through reimbursement for OMIDRIA under Medicare Part B expired on October 1, 2020. In December 2020, in its annual rule on Outpatient Prospective Payments System (“OPPS”) and ASC payments, CMS confirmed that OMIDRIA qualifies for separate payment when used on Medicare Part B patients in ASCs under CMS’ policy for non-opioid pain management surgical drugs. We believe that CMS will not change its separate payment policy for non-opioid pain management surgical drugs, which has been in effect since 2019.

Clinical Development Programs

Our clinical stage development programs include:

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

FDA is currently reviewing our BLA for narsoplimab in HSCT-TMA, and Phase 3 clinical programs are in process for narsoplimab in IgA nephropathy and aHUS. Narsoplimab is also being evaluated for treatment of COVID-19 in a late-stage adaptive platform trial and has been administered under compassionate use to treat COVID-19 patients in Italy and in the U.S.

Narsoplimab has received multiple designations from FDA and from the EMA across 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 and (2) 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 been granted designation as an orphan medicinal product for the treatment of primary IgA nephropathy.
- **aHUS:** In the U.S., narsoplimab has received from the FDA (1) fast-track designation for the treatment of patients with aHUS and (2) orphan drug designation for the prevention (inhibition) of complement-mediated thrombotic microangiopathies.

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

The primary efficacy endpoint in the trial was the proportion of patients who achieved designated “responder” status based on improvement in HSCT-TMA laboratory markers and clinical status. This is referred to as the

“complete response rate.” The primary laboratory markers that were evaluated were platelet count and lactate dehydrogenase (“LDH”) levels, while improvement in clinical status was evaluated based on organ function and transfusions. Each patient was required to show improvement in both laboratory markers and clinical status to be considered a responder. All others were considered non-responders.

Among patients who received at least one dose of narsoplimab, the complete response rate was 61% (95% confidence interval [CI] 40.6 to 78.5; $p < 0.0001$), while the complete response rate among patients who received the protocol-specified narsoplimab treatment of at least four weeks of dosing was 74% (95% CI 51.6 to 89.8; $p < 0.0001$). The response rates and their respective lower levels of the 95% confidence intervals are a multiple of the pre-specified efficacy threshold of 15%.

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

In November 2020, we completed the rolling submission to FDA of our BLA for narsoplimab for the treatment of HSCT-TMA. The BLA was accepted for filing by FDA and granted priority review, and we have responded to all information requests received to date. The FDA action date under the Prescription Drug User Fee Act (“PDUFA”) is July 17, 2021.

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

In our IgA nephropathy program, patient enrollment continues in the narsoplimab Phase 3 clinical trial, ARTEMIS-IGAN. The single Phase 3 trial design is a randomized, double-blind, placebo-controlled multicenter trial in patients at least 18 years of age with biopsy-confirmed IgA nephropathy and with 24-hour urine protein excretion greater than one gram per day at baseline on optimized renin-angiotensin system blockade. This trial includes a run-in period. Initially, patients are expected to receive an IV dose of study drug each week for 12 weeks; additional weekly dosing can be administered to achieve optimal response. The primary endpoint, which we believe could suffice for full or accelerated approval depending on the effect size, is reduction in proteinuria at 36 weeks after the start of dosing. The trial is designed to allow intra-trial adjustment in sample size. For the purposes of safety and efficacy assessments, the initial sample size for the proteinuria endpoint is estimated at 140 patients in each of the treatment and placebo groups. This will include a subset of patients (78 per arm) 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. The trial

includes multiple sites in the U.S., Asia and Europe, though enrollment has been slow in part due to prioritizing the use of resources within our narsoplimab programs on HSCT-TMA, COVID-19 and IgA nephropathy.

- *MASP-2 - narsoplimab (OMS721) - COVID-19*. In March 2020, in response to a request from physicians at the Papa Giovanni XXIII Hospital in Bergamo, Italy, we initiated a compassionate use program for narsoplimab to treat patients with severe COVID-19 requiring mechanical ventilation.

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

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

All six patients were evaluated five to six months after cessation of narsoplimab treatment. None of them showed any clinical or laboratory evidence of long-term effects of COVID-19, such as cognitive impairment or cardiac, pulmonary or other organ disorder, commonly seen following resolution of initial COVID-19 symptoms.

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

Following treatment of the initial six patients under the compassionate use program in Italy, we continued compassionate-use treatment in the U.S. and Italy. Prior to receiving narsoplimab, all of the patients in this second cohort were severely ill, mechanically ventilated, had multiple comorbidities, and had failed other therapies, including anti-virals, targeted anti-inflammatory therapeutics, convalescent plasma and steroids. Following treatment with narsoplimab, the laboratory improvements and clinical outcomes of these patients are similar to those seen in the initial cohort of Bergamo patients.

Narsoplimab is also the only complement inhibitor included in the I-SPY COVID-19 platform trial sponsored by Quantum Leap Healthcare Collaborative, which is evaluating investigational therapies for the treatment of critically ill COVID-19 patients. The trial utilizes Quantum Leap Healthcare Collaborative's adaptive platform

trial design, which is intended to increase trial efficiency by minimizing the number of participants and time required to evaluate potential treatments.

Discussions regarding the use of narsoplimab in COVID-19 with leaders across various government agencies, both in the U.S. and internationally, continue to progress.

- MASP-3 - OMS906 - Alternative Pathway Disorders. As part of our MASP program, we have identified mannan-binding lectin-associated serine protease-3 (“MASP-3”), which has been shown to be the key activator of the complement system’s alternative pathway (“APC”), and we believe that we are the first to make this and related discoveries associated with the APC. The complement system is part of the immune system’s innate response, and the APC is considered the amplification loop within the complement system. MASP-3 is responsible for the conversion of pro-factor D to factor D; converted factor D is necessary for the activation of the APC. Based on our alternative pathway-related discoveries, we have expanded our intellectual property position to protect our inventions stemming from these discoveries beyond MASP-2-associated inhibition of the lectin pathway to include inhibition of the alternative pathway. Our current primary focus in this program is developing MASP-3 inhibitors for the treatment of disorders related to the APC. We believe that MASP-3 inhibitors have the potential to treat patients suffering from a wide range of diseases and conditions, including: paroxysmal nocturnal hemoglobinuria (“PNH”); multiple sclerosis; neuromyelitis optica; age-related macular degeneration; Alzheimer’s disease; systemic lupus erythematosus; diabetic retinopathy; chronic obstructive pulmonary disease; antineutrophil cytoplasmic antibody-associated vasculitis; anti-phospholipid syndrome; atherosclerosis; myasthenia gravis and others. Our OMS906 monoclonal antibody program has generated positive data in well-established animal models of PNH and rheumatoid arthritis as well as strong pharmacodynamic activity in non-human primates.

In September 2020 we began enrollment and dosing in a placebo-controlled, double-blind, single-ascending-dose and multiple-ascending-dose Phase 1 clinical trial to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of OMS906. We have completed dosing all of the intravenous dosing cohorts and the first subcutaneous dosing cohort in the single-ascending dose study. Initial data from the Phase 1 trial are expected in the second quarter of 2021.

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

In the double blind, randomized Phase 1 study, the study drug, referred to as OMS182399, met the primary endpoints of safety and tolerability and showed a favorable and dose-proportional pharmacokinetic profile supporting once-daily dosing. There was no apparent food effect on plasma exposure to OMS182399. Continued clinical development in our PDE7 program is subject to allocation of financial and other resources, which are currently prioritized for other programs. A manuscript detailing the mechanism of action of PDE7 inhibition in nicotine addiction has been accepted for publication in the peer-reviewed *Journal of Neuroscience*.

Preclinical Development Programs and Platforms

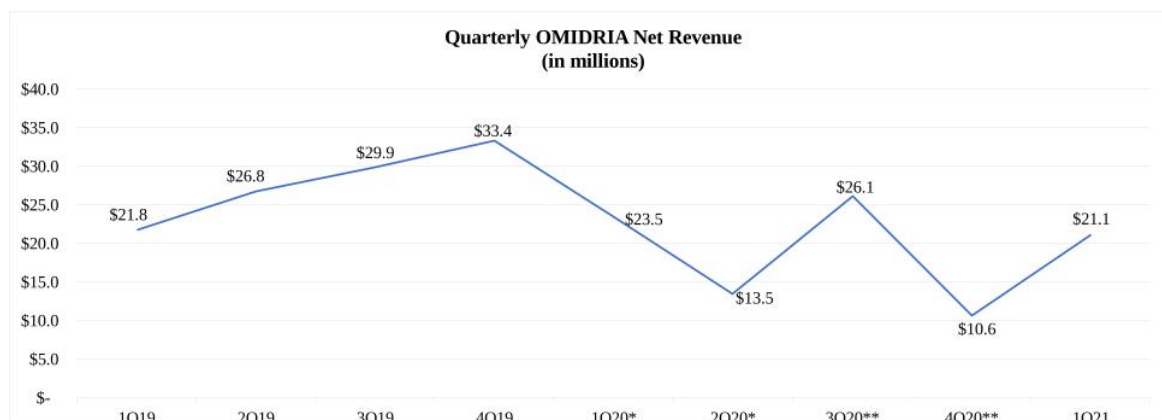
Our preclinical programs and platforms include:

- Other MASP Inhibitor Preclinical Programs. We have generated positive preclinical data from MASP-2 inhibition in *in vivo* models of age-related macular degeneration, myocardial infarction, diabetic neuropathy, stroke, traumatic brain injury, ischemia-reperfusion injury, and other diseases and disorders. We are also developing a longer-acting second generation antibody targeting MASP-2 for which we expect to initiate clinical trials in 2022. This program is designated “OMS1029.” Development efforts are also directed to a small-molecule inhibitor of MASP-2 designed for oral administration as well as to small-molecule inhibitors of MASP-3 and bispecific small- and large-molecule inhibitors of MASP-2/-3.

- GPR174 and GPCR Platform.*** We have developed a proprietary cellular redistribution assay which we use in a high-throughput manner to identify synthetic ligands, including antagonists, agonists and inverse agonists, that bind to and affect the function of orphan GPCRs. We have screened Class A orphan GPCRs against our small-molecule chemical libraries using the cellular redistribution assay and have identified and confirmed compounds that interact with 54 of the 81 Class A orphan GPCRs linked to a wide range of indications including cancer as well as metabolic, cardiovascular, immunologic, inflammatory and central nervous system disorders. One of our priorities in this program is GPR174, which is involved in the modulation of the immune system. In *ex vivo* human studies, our small-molecule inhibitors targeting GPR174 upregulate the production of cytokines, block multiple checkpoints and tumor promoters, and suppress regulatory T-cells. Based on our data, we believe that GPR174 controls a major, previously unrecognized pathway in cancer and modulation of the receptor could provide a seminal advance in immuno-oncologic treatments for a wide range of tumors. Our studies in mouse models of melanoma and colon carcinoma found that GPR174-deficiency resulted in significantly reduced tumor growth and improved survival of the animals versus normal mice. Our discoveries suggest a new approach to cancer immunotherapy that targets inhibition of GPR174 and can be combined with and significantly improve the tumor-killing effects of other oncologic agents, including radiation, adenosine pathway inhibitors and checkpoint inhibitors. These discoveries include (1) identification of cancer-immunity pathways controlled by GPR174, (2) the identification of phosphatidylserine as a natural ligand for GPR174, (3) a collection of novel small-molecule inhibitors of GPR174 and (4) a synergistic enhancement of “tumor-fighting” cytokine production by T cells following the combined inhibition of both GPR174 and the adenosine pathway, another key metabolic pathway that regulates tumor immunity. We are developing both small-molecule and antibody inhibitors of GPR174 with the objective of moving compounds into human trials and exploring several of our other GPCR targets as well.

Financial Summary

We recognized net losses of \$35.1 million and \$29.0 million for the three months ended March 31, 2021 and 2020, respectively, and our OMIDRIA net revenues were \$21.1 million and \$23.5 million for the same periods. As of March 31, 2021, we had \$100.5 million in cash and cash equivalents and short-term investments available for general corporate use and \$24.8 million in accounts receivable, net.



* Fiscal quarters with significantly reduced cataract procedures due to COVID-19

** Pass-through reimbursement expired on October 1, 2020. In December 2020, separate payment was confirmed for OMIDRIA, effective retroactively as of October 1, 2020.

Pass-through reimbursement for OMIDRIA under Medicare Part B expired on October 1, 2020, which negatively affected our net revenues for September, the fourth quarter of 2020 and the first quarter of 2021. In December 2020, CMS confirmed that OMIDRIA qualifies for separate payment when used on Medicare Part B patients in ASCs. CMS’ current non-opioid separate payment policy can be changed by CMS through its OPPS/ASC annual rulemaking and

comment process. We believe CMS will continue its separate payment policy for non-opioid pain management surgical drugs, which has been in effect since 2019, and that OMIDRIA will continue to be separately reimbursed when used in the ASC setting.

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

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	
	2021	2020
	(In thousands)	
Product sales, net	\$ 21,061	\$ 23,537

During the three months ended March 31, 2021, OMIDRIA net revenue was \$21.1 million as compared to \$23.5 million for the three months ended March 31, 2020. The decrease in revenue during the three months ended March 31, 2021 compared to the same period in the prior year was due to the timing of ASCs' ability to verify reimbursement status following the December confirmation by CMS of separate payment for OMIDRIA before resuming their OMIDRIA usage. The lack of Medicare Part B reimbursement in the hospital setting during the quarter ended March 31, 2021 also contributed to the decrease in revenues. The ongoing COVID-19 pandemic negatively affected the number of cataract procedures performed in the quarter ended March 31, 2020 and, to a lesser extent, the quarter ended March 31, 2021. With separate payment for OMIDRIA established, we expect OMIDRIA revenues to increase during the second quarter.

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 months ended March 31, 2021 was 31.5% of gross OMIDRIA product sales compared to 32.3% for the three months ended March 31, 2020. The decrease in gross-to-net deductions as a percentage of sales in 2021 compared to 2020 is due to a reduction in sales returns during the first quarter of 2021 partially offset by an increase in our OMIDRIAssure[®] patient assistance and reimbursement program.

A summary of our gross-to-net related accruals for the three months ended March 31, 2021 is as follows:

	Chargebacks and Rebates	Distribution Fees and Product Return Allowances (In thousands)	Total
Balance as of December 31, 2020	3,740	948	4,688
Provisions	8,539	1,109	9,648
Payments	(5,399)	(582)	(5,981)
Balance as of March 31, 2021	<u>\$ 6,880</u>	<u>\$ 1,475</u>	<u>\$ 8,355</u>

Chargebacks and Rebates

We record a provision for estimated chargebacks and rebates at the time we recognize OMIDRIA product sales revenue and reduce the accrual when payments are made or credits are granted. Our chargebacks are related to a

pharmaceutical pricing agreement, a federal supply schedule agreement, a 340B prime vendor agreement, a Medicaid drug rebate agreement and an off-invoice discount to our ASC and hospital customers. We also record a provision for our OMIDRIA patient assistance and reimbursement program and for 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; internal, overhead and other expenses; and stock-based compensation expense. The following table illustrates our expenses associated with these activities:

	March 31,	
	2021	2020
	(In thousands)	
Direct external expenses:		
Clinical research and development:		
MASP-2 program - OMS721 (narsoplimab)	\$ 17,031	\$ 13,215
MASP-3 program - OMS906	1,771	—
OMIDRIA - Ophthalmology	565	626
PDE7 - OMS527	142	1,337
Total clinical research and development	19,509	15,178
Preclinical research and development	2,711	3,515
Total direct external expenses	22,220	18,693
Internal, overhead and other expenses	9,657	8,771
Stock-based compensation expense	1,480	1,447
Total research and development expenses	\$ 33,357	\$ 28,911

Total clinical research and development expenses increased \$4.3 million for the three months ended March 31, 2021 compared to the same period in the prior year due to timing of narsoplimab drug manufacturing and medical affairs-related activities surrounding the commercial launch of narsoplimab. During the first quarter of 2021, OMS906 clinical research and development expenses were \$1.8 million, which also contributed to the increase in total clinical research and development expenses. In the prior year quarter, OMS906 expenses of \$2.3 million were included as preclinical research and development.

The decrease in preclinical research and development expenses for the three months ended March 31, 2021 compared to the same period in the prior year is primarily due to the migration of OMS906 from preclinical research and development to clinical research and development beginning in the third quarter of 2020 when OMS906 entered Phase 1 clinical trials.

The increases in internal, overhead and other expenses are primarily due to additional employee-related costs and additional leased laboratory facilities to support our research and development activities.

We expect overall research and development costs in the second quarter of 2021 to be comparable to the quarter ended March 31, 2021.

At this time, we are unable to estimate with certainty the longer-term costs we will incur in the continued development of our product candidates due to the inherently unpredictable nature of our preclinical and clinical development activities as well as to the potential impacts of the COVID-19 pandemic. Clinical development timelines, the probability of success and development costs can differ materially as new data become available and as expectations change. Our future research and development expenses will depend, in part, on the preclinical or clinical success of each product candidate as well as on 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	
	2021	2020
	(In thousands)	
Selling, general and administrative expenses, excluding stock-based compensation expense	\$ 16,261	\$ 16,007
Stock-based compensation expense	1,791	2,029
Total selling, general and administrative expenses	<u>\$ 18,052</u>	<u>\$ 18,036</u>

Total selling, general and administrative expenses did not increase significantly compared to the same period in the prior year.

We expect that our selling, general and administrative expenses will increase during the second quarter of 2021 due to increased pre-commercialization activities for narsoplimab.

Interest Expense

	Three Months Ended	
	2021	2020
	March 31,	
	(In thousands)	
Interest expense	\$ 4,897	\$ 5,903

Interest expense is comprised of contractual interest and amortization of debt issuance and debt discount related to our 2023 and 2026 Notes as well as to interest on our finance leases. Interest expense decreased \$1.0 million for the three months ended March 31, 2021 compared to the same period in the prior year due to the early adoption of ASU 2020-06, which eliminated the amortization of the non-cash debt discount on the 2023 and 2026 Notes. This decrease was partially offset by the increase in interest related to our 2026 Notes, which were issued in August and September 2020 (for more information, see "Note 7—Unsecured Convertible Senior Notes").

Financial Condition - Liquidity and Capital Resources

As of March 31, 2021, we had \$100.5 million in cash, cash equivalents and short-term investments available for general corporate use held primarily in money-market accounts as compared to \$135.0 million at December 31, 2020. In addition, as of March 31, 2021, we had \$24.8 million in accounts receivable, net. We have historically generated net losses and incurred negative cash flows from operations and debt service. For the three months ended March 31, 2021,

we incurred a net loss of \$35.1 million and incurred negative cash flows from operations of \$40.3 million. The net loss and the negative cash flows from operations in the quarter ended March 31, 2021 were significantly affected by (1) reduced OMIDRIA revenues following expiration of the drug's pass-through status and the delayed posting by Medicare Administrative Contractors of CMS' December 2020 determination that OMIDRIA be paid separately under Medicare Part B in the ASC setting, and (2) the COVID-19-related decrease in the number of cataract procedures performed nationally.

FDA accepted our BLA for narsoplimab in HSCT-TMA for priority review with a PDUFA action date of July 17, 2021. We anticipate, but cannot guarantee, that narsoplimab will receive FDA approval and launch in the U.S. in 2021. If approved, we cannot fully predict the timing or the magnitude of narsoplimab revenues, but we believe they will be significant. Our sales and marketing strategies for the launch of narsoplimab for HSCT-TMA include various milestones at which we commit to incremental spending, such as for field sales hiring, providing for flexibility in the timing of costs incurred should the approval of narsoplimab be delayed.

We plan to fund our operations for the next twelve months with our cash and investments on hand from sales of OMIDRIA and, if FDA approval is granted, from sales of narsoplimab for HSCT-TMA. In addition, we may utilize funds available under our line of credit, which allows us to borrow up to 85% of our available accounts receivable borrowing base, less certain reserves, or \$50.0 million, whichever is less. We also entered into a sales agreement to sell shares of our common stock, from time to time, up to an aggregate offering amount of \$150.0 million through an "at the market" equity offering program. Should it be necessary or determined to be strategically advantageous, we could pursue debt financings as well as public and private offerings of our equity securities, similar to those we have previously completed, or other strategic transactions, which may include licensing a portion of our existing technology. Should it be necessary to manage our operating expenses, we would reduce our projected cash requirements through reduction of our expenses by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

Cash Flow Data

	Three Months Ended March 31,	
	2021	2020
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	\$ (40,254)	\$ (9,141)
Investing activities	\$ 32,985	\$ 10,776
Financing activities	\$ 5,796	\$ 2,399

Operating Activities. Net cash used in operating activities for the three months ended March 31, 2021 increased by \$31.1 million as compared to the same period in 2020. The net increase is primarily due to a \$32.1 million reduction in accounts receivable cash collections, a \$6.1 million increase in our net loss and a \$2.3 million decrease in non-cash charges offset by \$4.4 million decrease in prepaids and a \$4.7 million increase in accounts payable and accrued expenses.

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 three months ended March 31, 2021 was \$33.0 million, an increase of \$22.2 million for the same period in 2020 due to net proceeds from investment maturities exceeding investment purchases.

Financing Activities. Net cash provided by financing activities during the three months ended March 31, 2021 was \$5.8 million, an increase of \$3.4 million compared to the same period in 2020. The increase was due to incremental cash proceeds from the exercise of our common stock.

At the Market Sales Agreement. On March 1, 2021, we entered into a sales agreement to sell shares of our common stock, from time to time and having an aggregate offering price of up to \$150.0 million, through an “at the market” equity offering program. As of March 31, 2021, we have not sold any shares under this agreement.

Line of Credit Agreement. Our Line of Credit Agreement with Silicon Valley Bank provides for a \$50.0 million revolving line of credit facility. Under the Line of Credit Agreement we may draw, on a revolving basis, up to the lesser of \$50.0 million or 85.0% of our eligible accounts receivable, less certain reserves. The Line of Credit Agreement is secured by all of our assets, excluding intellectual property and development program inventories, and matures on August 2, 2022. As of March 31, 2021, we had no outstanding borrowings under the Line of Credit Agreement, and we were in compliance with all covenants in all material respects. See earlier discussion under “Liquidity and Capital Resources” for further detail regarding the availability of the line of credit.

Contractual Obligations and Commitments

Our future minimum contractual commitments and obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2020. Other than the following, our future minimum contractual obligations and commitments have not changed materially from the amounts previously reported.

Lease Agreements

Our lease for our office and laboratory space ends in November 2027. We have two five-year options to extend the lease term. As of March 31, 2021, the remaining aggregate non-cancelable rent payable under the initial term of the lease, excluding common area maintenance and related operating expenses, is \$53.8 million.

Goods and Services

We have certain other non-cancelable obligations under various agreements that relate to goods and services. As of March 31, 2021, our aggregate firm commitments were \$30.9 million.

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

Critical Accounting Policies and Significant Judgments and Estimates

On January 1, 2021, we adopted ASU 2020-06, *Debt—Debt with Conversion Options* (Subtopic 470-20) and *Derivatives and Hedging—Contracts in Entity’s Own Equity* (Subtopic 815-40) on a modified retrospective basis (for more information, see “Note 2—Significant Accounting Policies, Recently Adopted Pronouncements”).

Other than the adoption of ASU 2020-06, 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, 2020.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is primarily confined to our investment securities. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities. As of March 31, 2021, we had cash, cash equivalents and short-term investments of \$100.5 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These securities in our investment portfolio are not leveraged and are classified as available-for-sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a materially 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 March 31, 2021. 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 March 31, 2021, 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, 2020, as filed with the SEC on March 1, 2021. In assessing the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2020, 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.

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

We issued 24,901 shares of our common stock upon the cashless net exercise of a warrant to purchase 43,115 shares of our common stock during the three months ended March 31, 2021. The warrant was issued on May 18, 2016 in connection with the amendment of a previous loan agreement. We deemed the issuance of common stock upon the exercise of the warrant to be exempt from registration under the Securities Act pursuant to Section 3(a)(9) of the Securities Act. No underwriters were involved in the issuance of our common stock upon the exercise of the warrant and no commissions were paid in connection with such issuance.

ITEM 6. EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
10.1†	Platform Development Funding Agreement between Omeros Corporation and Vulcan Inc. and its affiliate dated October 21, 2010 (previously filed as Exhibit 10.44 from the Company’s Annual Report on Form 10-K filed on March 15, 2011)
10.2†	Grant Award Agreement between Omeros Corporation and the Life Sciences Discovery Fund Authority dated October 21, 2010 (previously filed as Exhibit 10.45 from the Company’s Annual Report on Form 10-K filed on March 15, 2011)
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Link base Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document

104.1 Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101)

† Confidential portions of this Exhibit were redacted pursuant to Item 601(b)(10) of Regulation S-K and the Company agrees to furnish supplementary to the Securities and Exchange Commission a copy of any redacted information or omitted schedule and/or exhibit upon request.

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

SIGNATURES

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

OMEROS CORPORATION

Dated: May 10, 2021

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

Dated: May 10, 2021

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

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

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

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

Dated: May 10, 2021

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

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

I, Michael A. Jacobsen, certify that:

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

Dated: May 10, 2021

/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 March 31, 2021, 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: May 10, 2021

/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 March 31, 2021, 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: May 10, 2021

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer
