
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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)

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

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

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, par value \$0.01 per share	OMER	The Nasdaq Stock Market LLC

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

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

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

As of November 7, 2023, the number of outstanding shares of the registrant’s common stock, par value \$0.01 per share, was 62,865,491.

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 currently available information. All statements other than statements of historical fact are “forward-looking statements.” Terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “likely,” “look forward to,” “may,” “objective,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “slate,” “target,” “will,” “would,” and similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

- our estimates of future operating expenses and projections regarding how long our existing cash, cash equivalents, short-term investments, royalty receipts and potential revenues will fund our anticipated operating expenses, capital expenditures and debt service obligations;
 - our expectations related to future royalties potentially payable to us under the terms of the asset purchase agreement under which we divested our former commercial ophthalmology product OMIDRIA®;
 - our expectations regarding clinical plans and anticipated or potential paths to regulatory approval of narsoplimab by the U.S. Food and Drug Administration (“FDA”) and the European Medicines Agency (“EMA”) in hematopoietic stem cell transplant-associated thrombotic microangiopathy (“HSCT-TMA”), COVID-19 or any other indication;
 - whether and when a marketing authorization application (“MAA”) may be filed with the EMA for narsoplimab in any indication, and whether the EMA will grant approval for narsoplimab in any indication;
 - our plans for the commercial launch of narsoplimab following any regulatory approval and our estimates and expectations regarding coverage and reimbursement for any approved products;
 - our expectation that we will rely on contract manufacturers to manufacture narsoplimab, if approved, for commercial sale and to manufacture our drug candidates for purposes of clinical supply and in anticipation of potential commercialization;
 - our expectations regarding the clinical, therapeutic and competitive benefits and importance of our drug candidates;
 - our ability to design, initiate and/or successfully complete clinical trials and other studies for our drug candidates and our plans and expectations regarding our ongoing or planned clinical trials;
 - 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 (“EC”), or the EMA; and whether we can capitalize on the regulatory incentives provided by fast-track or breakthrough therapy designations granted by FDA;
 - 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 our drug candidates, if commercialized, face or may face;
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- 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, and drug 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 (the “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 differ materially from current expectations. Except as required by applicable law, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

OMEROS CORPORATION
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2023

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

OMEROS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,640	\$ 11,009
Short-term investments	279,670	183,909
OMIDRIA contract royalty asset, short-term	29,228	28,797
Receivables	6,878	213,221
Prepaid expense and other assets	4,922	6,300
Total current assets	351,338	443,236
OMIDRIA contract royalty asset	119,502	123,425
Right of use assets	19,460	21,762
Property and equipment, net	1,717	1,492
Restricted investments	1,054	1,054
Total assets	\$ 493,071	\$ 590,969
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 5,866	\$ 5,989
Accrued expenses	34,859	30,551
Current portion of unsecured convertible senior notes, net	94,909	94,381
Current portion of OMIDRIA royalty obligation	6,654	1,152
Current portion of lease liabilities	4,888	4,310
Total current liabilities	147,176	136,383
Unsecured convertible senior notes, net	221,828	220,906
OMIDRIA royalty obligation	118,770	125,126
Lease liabilities, non-current	19,249	22,426
Other accrued liabilities, non-current	—	444
Commitments and contingencies (Note 10)		
Shareholders' equity (deficit):		
Preferred stock, par value \$0.01 per share, 20,000,000 shares authorized; none issued and outstanding at September 30, 2023 and December 31, 2022.	—	—
Common stock, par value \$0.01 per share, 150,000,000 shares authorized at September 30, 2023 and December 31, 2022; 62,865,491 and 62,828,765 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively.	628	628
Additional paid-in capital	729,882	720,773
Accumulated deficit	(744,462)	(635,717)
Total shareholders' equity (deficit)	(13,952)	85,684
Total liabilities and shareholders' equity (deficit)	\$ 493,071	\$ 590,969

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Costs and expenses:				
Research and development	\$ 31,731	\$ 38,568	\$ 85,980	\$ 86,172
Selling, general and administrative	16,422	12,198	38,785	37,079
Total costs and expenses	48,153	50,766	124,765	123,251
Loss from operations	(48,153)	(50,766)	(124,765)	(123,251)
Interest expense	(7,916)	(4,932)	(23,781)	(14,799)
Interest and other income	4,413	906	12,913	2,069
Net loss from continuing operations	(51,656)	(54,792)	(135,633)	(135,981)
Net income from discontinued operations, net of tax	13,906	37,336	26,888	54,665
Net loss	\$ (37,750)	\$ (17,456)	\$ (108,745)	\$ (81,316)
Basic and diluted net income (loss) per share:				
Net loss from continuing operations	\$ (0.82)	\$ (0.87)	\$ (2.16)	\$ (2.17)
Net income from discontinued operations	0.22	0.59	0.43	0.87
Net loss	\$ (0.60)	\$ (0.28)	\$ (1.73)	\$ (1.30)
Weighted-average shares used to compute basic and diluted net income (loss) per share	62,856,721	62,730,015	62,840,990	62,728,276

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share data)

(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance at January 1, 2023	62,828,765	\$ 628	\$ 720,773	\$ (635,717)	\$ 85,684
Stock-based compensation expense	—	—	2,953	—	2,953
Net loss	—	—	—	(33,701)	(33,701)
Balance at March 31, 2023	62,828,765	628	723,726	(669,418)	54,936
Exercise of stock options	19,556	—	97	—	97
Stock-based compensation expense	—	—	2,771	—	2,771
Net loss	—	—	—	(37,294)	(37,294)
Balance at June 30, 2023	62,848,321	628	726,594	(706,712)	20,510
Exercise of stock options	17,170	—	53	—	53
Stock-based compensation expense	—	—	3,235	—	3,235
Net loss	—	—	—	(37,750)	(37,750)
Balance at September 30, 2023	<u>62,865,491</u>	<u>\$ 628</u>	<u>\$ 729,882</u>	<u>\$ (744,462)</u>	<u>\$ (13,952)</u>
Balance at January 1, 2022	62,628,855	\$ 626	\$ 706,288	\$ (683,134)	\$ 23,780
Exercise of stock options	101,160	1	413	—	414
Stock-based compensation expense	—	—	3,892	—	3,892
Net loss	—	—	—	(33,011)	(33,011)
Balance at March 31, 2022	62,730,015	627	710,593	(716,145)	(4,925)
Stock-based compensation expense	—	—	3,072	—	3,072
Net loss	—	—	—	(30,849)	(30,849)
Balance at June 30, 2022	62,730,015	627	713,665	(746,994)	(32,702)
Stock-based compensation expense	—	—	3,844	—	3,844
Net loss	—	—	—	(17,456)	(17,456)
Balance at September 30, 2022	<u>62,730,015</u>	<u>\$ 627</u>	<u>\$ 717,509</u>	<u>\$ (764,450)</u>	<u>\$ (46,314)</u>

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2023	2022
Operating activities:		
Net loss	\$ (108,745)	\$ (81,316)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,959	10,808
Non-cash interest expense on unsecured convertible debt	1,450	1,361
Depreciation and amortization	715	789
Non-cash interest earned on OMIDRIA contract royalty asset	(11,484)	(13,739)
Remeasurement on OMIDRIA contract royalty asset	(14,924)	(40,631)
Accretion on U.S. government treasury bills, net	(7,280)	—
Early termination of operating lease	—	(454)
Changes in operating assets and liabilities:		
Receivables	206,343	24,301
Prepaid expenses and other	876	1,769
OMIDRIA contract royalty asset	29,900	47,555
Accounts payable and accrued expense	3,741	(11,544)
Net cash provided by (used in) operating activities	<u>109,551</u>	<u>(61,101)</u>
Investing activities:		
Purchases of investments and other	(839,595)	(103,573)
Proceeds from the sale and maturities of investments	751,114	84,600
Purchases of property and equipment	(308)	(100)
Net cash used in investing activities	<u>(88,789)</u>	<u>(19,073)</u>
Financing activities:		
Proceeds from sale of future royalties	—	125,000
Principal payments on OMIDRIA royalty obligation	(854)	—
Principal payments on finance lease obligations	(427)	(515)
Proceeds upon exercise of stock options and warrants	150	414
Net cash provided by (used in) financing activities	<u>(1,131)</u>	<u>124,899</u>
Net increase in cash and cash equivalents	19,631	44,725
Cash and cash equivalents at beginning of period	11,009	100,808
Cash and cash equivalents at end of period	<u>\$ 30,640</u>	<u>\$ 145,533</u>
Supplemental cash flow information		
Cash paid for interest	<u>\$ 23,801</u>	<u>\$ 13,437</u>
Property acquired under finance lease	<u>\$ 632</u>	<u>\$ 806</u>

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Basis of Presentation*General*

Omeros Corporation (“Omeros,” the “Company” or “we”) is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting immunologic disorders, including complement-mediated diseases, cancers and addictive and compulsive disorders. We marketed our first drug product, OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% for use during cataract surgery or intraocular lens replacement in the United States (the “U.S.”) until we sold OMIDRIA and related business assets on December 23, 2021 (see “Sale of OMIDRIA Assets” below for additional information).

Our pipeline of clinical-stage development programs includes: narsoplimab, our antibody targeting mannan-binding lectin-associated serine protease 2 (“MASP-2”), the effector enzyme of the lectin pathway of complement; OMS1029, our long-acting antibody targeting MASP-2; OMS906, our antibody targeting mannan-binding lectin-associated serine protease-3 (“MASP-3”), the key activator of the alternative pathway of complement; and OMS527, our phosphodiesterase 7 (“PDE7”) inhibitor.

In October 2023, we announced the results of a pre-specified interim analysis of our Phase 3 ARTEMIS-IGAN trial evaluating narsoplimab for the treatment of immunoglobulin A (“IgA”) nephropathy. Topline results showed that narsoplimab did not reach statistically significant improvement over placebo on the primary endpoint of reduction in proteinuria. Based on this result, we have discontinued the ARTEMIS-IGAN clinical trial. Clinical development of narsoplimab is currently focused primarily on hematopoietic stem cell transplant-associated thrombotic microangiopathy (“HSCT-TMA”). Our Biologics License Application (“BLA”) for narsoplimab in HSCT-TMA is anticipated to be resubmitted with additional information to support potential approval of narsoplimab in this indication. Phase 1 and Phase 2 clinical programs are underway in our other clinical-stage assets.

Sale of OMIDRIA Assets

On December 23, 2021, we sold our commercial product OMIDRIA and certain related assets including inventory and prepaid expenses to Rayner Surgical Inc. (“Rayner”). Rayner paid us \$126.0 million in cash at closing, and we retained all outstanding accounts receivable, accounts payable and accrued expenses as of the closing date.

Under the Asset Purchase Agreement with Rayner (the “Asset Purchase Agreement”), we were entitled to receive a milestone payment of \$200.0 million (the “Milestone Payment”) within 30 days following an event (the “Milestone Event”) that establishes separate payment for OMIDRIA for a continuous period of at least four years when furnished in the ambulatory surgery center (“ASC”) setting. In December 2022, the Milestone Event occurred and we recorded a \$200.0 million milestone receivable. Upon the achievement of the Milestone Event, our royalties on U.S. net sales were reduced from 50% to 30% with royalties on net sales outside the U.S. remaining unchanged at 15%. We received the Milestone Payment together with accrued interest in February 2023.

As a result of the divestiture, the results of OMIDRIA operations (e.g., revenues and operating costs) are included in discontinued operations in our condensed consolidated statements of operations and comprehensive loss and excluded from continuing operations for all periods presented (See “Note 3 – Discontinued Operations”).

Basis of Presentation

Our condensed consolidated financial statements include the financial position and results of operations of Omeros and our wholly owned subsidiaries. All inter-company transactions have been eliminated. The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”).

Liquidity and Capital Resources

As of September 30, 2023, we had cash, cash equivalents and short-term investments of \$310.3 million. Our loss for the quarter ended September 30, 2023 was \$37.8 million and our cash provided by operations for the nine months ended September 30, 2023 was \$109.6 million, which included collection of the \$200.0 million Milestone Payment in the first quarter of 2023. We have a \$95.0 million principal payment due at maturity on our 2023 unsecured convertible senior notes on November 15, 2023, which we expect to pay on the maturity date from our existing cash and investments on hand.

Historically, we have incurred net losses from continuing operations and negative operating cash flows. We have not yet established an ongoing source of revenue sufficient to cover our operating costs; therefore, we would need to continue to raise additional capital to accomplish our business plan and to retire our outstanding convertible senior notes due in 2026. We plan to continue to fund our operations for at least the next twelve months with our existing cash, investments and royalties from Rayner. We have a sales agreement in place for an “at the market” equity offering facility through which we may offer and sell shares of our common stock equaling an aggregate amount up to \$150.0 million. Should it be determined to be strategically advantageous, we could also 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 technologies. Should it be necessary to manage our operating expenses, we could also 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 OMIDRIA contract royalty asset valuation, stock-based compensation expense, and accruals for clinical trials and manufacturing of drug product. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from these estimates.

Note 2—Significant Accounting Policies

OMIDRIA Royalties, Milestones and Contract Royalty Assets

We have rights to receive future royalties from Rayner on OMIDRIA net sales at royalty rates that vary based on geography and certain regulatory contingencies. Therefore, future OMIDRIA royalties are treated as variable consideration. The sale of OMIDRIA qualified as an asset sale under GAAP. To measure the OMIDRIA contract royalty asset we used the expected value approach, which is the sum of the discounted probability-weighted royalty payments we would receive using a range of potential outcomes to the extent that it is probable that a significant reversal in the amount of cumulative income recognized will not occur. As contemplated by the Asset Purchase Agreement, the royalty rate applicable to U.S. net sales of OMIDRIA was reduced from 50% to 30% upon the occurrence, in December 2022, of the event triggering the \$200.0 million Milestone Payment. Consequently, in December 2022, we revalued the OMIDRIA contract royalty asset using the 30% royalty rate on U.S. net sales and adjusted the probability-weighted outcomes to reflect the occurrence of the Milestone Event. Royalties earned are recorded as a reduction to the OMIDRIA contract royalty asset. The amount recorded in discontinued operations in future periods will reflect interest earned on the outstanding OMIDRIA contract royalty asset at an effective interest rate of 11.0% and any amounts we receive that are different from the expected royalties. The OMIDRIA contract royalty asset will be re-measured periodically using the expected value approach based on actual results and future expectations. Any required adjustment to the OMIDRIA contract royalty asset will be recorded in discontinued operations.

OMIDRIA Royalty Obligation

On September 30, 2022, we sold to DRI Healthcare Acquisitions LP (“DRI”) an interest in a portion of our future OMIDRIA royalty receipts for a purchase price of \$125.0 million in cash (see “Note 8 – OMIDRIA Royalty Obligation”).

The \$125.0 million cash consideration obtained is classified as a liability and is recorded as an “OMIDRIA royalty obligation” on our condensed consolidated balance sheet. The liability is being amortized over the term of the arrangement using the implied effective interest rate of 9.4% and interest expense is recorded as a component of continuing operations.

To the extent our estimates of future royalties differ materially from previous estimates, we will adjust the carrying amount of the liability for future OMIDRIA royalties to the present value of the revised estimated cash flows, discounted at the original effective interest rate of 9.4% utilizing the cumulative catch-up method. The offset to the adjustment would be recognized as a component of net income (loss) from continuing operations.

Inventory

We expense inventory costs related to product candidates as research and development expenses until regulatory approval is reasonably assured in the U.S. or the European Union (“EU”). Once approval is reasonably assured, costs, including amounts related to third-party manufacturing, transportation and internal labor and overhead, will be capitalized.

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 lease obligations 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 finance lease obligations 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 an operating expense.

Stock-Based Compensation

Stock-based compensation expense is recognized for all share-based payments, including grants of stock option awards and restricted stock units (“RSU”) based on estimated fair values. The fair value of our stock is calculated using the Black-Scholes valuation model, which requires judgmental assumptions around volatility, risk-free rates, forfeiture rates and expected option life. Compensation expense is recognized over the 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 basis. 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.

Note 3—Discontinued Operations

On December 23, 2021, we sold OMIDRIA and certain related assets including inventory and prepaid expenses to Rayner.

Under the Asset Purchase Agreement, the achievement of the Milestone Event in December 2022 triggered a \$200.0 million Milestone Payment from Rayner and a reduction in the U.S. royalty rate from 50% to 30% on OMIDRIA net sales until the expiration or termination of the last issued and unexpired U.S. patent, which we expect to occur no earlier than 2033. The Milestone Event resulted in recognition of the \$200.0 million Milestone Payment, which we received in February 2023. Upon the occurrence of certain events described in the Asset Purchase Agreement, including during any specific period in which OMIDRIA is no longer eligible for separate payment, the U.S. base royalty rate would be further reduced to 10%.

The sale of OMIDRIA was recorded as an asset sale. Additionally, the results of operations related to OMIDRIA are recorded as income from discontinued operations for all periods presented in the condensed consolidated statements of operations and comprehensive loss.

The following schedule presents a roll forward of the OMIDRIA contract royalty asset (in thousands):

OMIDRIA contract royalty asset at December 31, 2022	\$	152,222
Royalties earned		(29,900)
Interest earned on OMIDRIA contract royalty asset		11,484
Remeasurement adjustments		14,924
OMIDRIA contract royalty asset at September 30, 2023	\$	<u>148,730</u>

Net income from discontinued operations is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Interest earned on OMIDRIA contract royalty asset	\$ 3,730	\$ 4,356	\$ 11,484	\$ 13,739
Remeasurement adjustments	10,100	32,917	14,924	40,631
Other income, net	76	63	480	295
Net income from discontinued operations, net of tax	<u>\$ 13,906</u>	<u>\$ 37,336</u>	<u>\$ 26,888</u>	<u>\$ 54,665</u>

Cash flow from discontinued operations is as follows:

	Nine Months Ended September 30,	
	2023	2022
	(In thousands)	
Net cash provided by discontinued operations from operating activities	\$ 232,081	\$ 60,188

Net cash provided by discontinued operations primarily represents royalties received and the \$200.0 million Milestone Payment that we collected from Rayner in February 2023.

Note 4—Net Loss Per Share

Our potentially dilutive securities include potential common shares related to our stock options, RSUs 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. 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
2026 Notes convertible to common stock (1)	12,172,008	12,172,008	12,172,008	12,172,008
2023 Notes convertible to common stock (1)	4,941,739	4,941,739	4,941,739	4,941,739
Outstanding options to purchase common stock	34,450	19,292	37,394	8,246
Outstanding restricted stock units	70,250	200,000	70,250	200,000
Total potentially dilutive shares excluded from net loss per share	17,218,446	17,333,039	17,221,390	17,321,993

(1) The 2023 Notes and 2026 Notes (defined below) are subject to capped call arrangements that potentially reduce the dilutive effect as described in “Note 7 — Unsecured Convertible Senior Notes.” Any potential impact of the capped call arrangements is excluded from this table.

Note 5—Certain Balance Sheet Accounts
OMIDRIA Contract Royalty Asset

The OMIDRIA contract royalty asset consists of the following:

	September 30, 2023	December 31, 2022
	(In thousands)	
Short-term contract royalty asset	\$ 29,228	\$ 28,797
Long-term contract royalty asset	119,502	123,425
Total OMIDRIA contract royalty asset	\$ 148,730	\$ 152,222

Receivables

Receivables consist of the following:

	September 30, 2023	December 31, 2022
	(In thousands)	
OMIDRIA royalty	\$ 6,658	\$ 12,966
Sublease and other	220	255
OMIDRIA milestone	—	200,000
Total receivables	\$ 6,878	\$ 213,221

Property and Equipment, Net

Property and equipment, net consists of the following:

	September 30, 2023	December 31, 2022
	(In thousands)	
Equipment under finance lease obligations	\$ 6,608	\$ 6,204
Laboratory equipment	3,407	3,135
Computer equipment	1,113	1,076
Office equipment and furniture	625	625
Total cost	11,753	11,040
Less accumulated depreciation and amortization	(10,036)	(9,548)
Total property and equipment, net	\$ 1,717	\$ 1,492

For the three months ended September 30, 2023 and 2022, depreciation and amortization expense was \$0.2 million and \$0.3 million, respectively. For the nine months ended September 30, 2023 and 2022, depreciation and amortization expense was \$0.7 million and \$0.8 million, respectively.

Accrued Expenses

Accrued expenses consists of the following:

	September 30, 2023	December 31, 2022
	(In thousands)	
Employee compensation	\$ 12,556	\$ 6,665
Clinical trials	9,351	5,536
Contract research and development	4,158	3,209
Interest payable	3,703	5,172
Consulting and professional fees	3,005	4,425
Income taxes payable	1,228	4,871
Other accrued expenses	858	673
Total accrued expenses	\$ 34,859	\$ 30,551

Note 6—Investments and Fair-Value Measurements

All of our investments are held in our name and are classified as short-term and held-to-maturity on the accompanying condensed consolidated balance sheets. Investment income is included as a component of other income on our condensed consolidated statement of operations and comprehensive loss. Investment income for the three months ended September 30, 2023 and September 30, 2022 consists primarily of interest earned of \$4.0 million and \$0.4 million, respectively. Investment income for the nine months ended September 30, 2023 and 2022 consists of interest income earned of \$11.7 million and \$0.6 million, respectively.

The following tables summarize our investments:

	September 30, 2023		
	Amortized Cost	Gross Unrealized Gains/(Losses) (In thousands)	Estimated Fair Value
U.S. government securities classified as short-term investments	\$ 127,385	\$ 2	\$ 127,387
Money-market funds classified as short-term investments	152,285	—	152,285
Total short-term investments	279,670	2	279,672
Certificate of deposit classified as non-current restricted investments	1,054	—	1,054
Total	\$ 280,724	\$ 2	\$ 280,726

	December 31, 2022		
	Gross Unrealized		Estimated Fair Value
	Amortized Cost	Gains/(Losses)	
		(In thousands)	
U.S. government securities classified as short-term investments	\$ 99,027	\$ 22	\$ 99,049
Money-market funds classified as short-term investments	84,882	—	84,882
Total short-term investments	183,909	22	183,931
Certificate of deposit classified as non-current restricted investments	1,054	—	1,054
Total	<u>\$ 184,963</u>	<u>\$ 22</u>	<u>\$ 184,985</u>

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 are as follows:

	September 30, 2023			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
U.S. government securities classified as short-term investments	\$ —	\$ 127,387	\$ —	\$ 127,387
Money-market funds classified as short-term investments	152,285	—	—	152,285
Total short-term investments	152,285	127,387	—	279,672
Certificate of deposit classified as non-current restricted investments	1,054	—	—	1,054
Total	<u>\$ 153,339</u>	<u>\$ 127,387</u>	<u>\$ —</u>	<u>\$ 280,726</u>

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
U.S. government securities classified as short-term investments	\$ —	\$ 99,049	\$ —	\$ 99,049
Money-market funds classified as short-term investments	84,882	—	—	84,882
Total short-term investments	84,882	99,049	—	183,931
Certificate of deposit classified as non-current restricted investments	1,054	—	—	1,054
Total	<u>\$ 85,936</u>	<u>\$ 99,049</u>	<u>\$ —</u>	<u>\$ 184,985</u>

Cash held in demand deposit accounts of \$30.6 million and \$11.0 million is excluded from our fair-value hierarchy disclosure as of September 30, 2023 and December 31, 2022, respectively. The carrying amounts reported in the accompanying condensed consolidated balance sheets for receivables, accounts payable and other current monetary assets and liabilities approximate fair value.

See “Note 7—Unsecured Convertible Senior Notes” and “Note 8—OMIDRIA Royalty Obligation” for the carrying amount and estimated fair value of our outstanding convertible senior notes and the OMIDRIA royalty obligation.

Note 7—Unsecured Convertible Senior Notes

We carry \$95.0 million in aggregate principal on our 6.25% Convertible Senior Notes (the “2023 Notes”) and \$225.0 million in aggregate principal on our 5.25% Convertible Senior Notes (the “2026 Notes”) as shown below:

	Balance as of September 30, 2023		
	2023 Notes	2026 Notes	Total
	(In thousands)		
Principal amount	\$ 95,000	\$ 225,030	\$ 320,030
Unamortized debt issuance costs	(91)	(3,202)	(3,293)
Total unsecured convertible senior notes, net	\$ 94,909	\$ 221,828	\$ 316,737
Fair value of outstanding unsecured convertible senior notes (1)	<u>\$ 94,822</u>	<u>\$ 136,424</u>	
	Balance as of December 31, 2022		
	2023 Notes	2026 Notes	Total
	(In thousands)		
Principal amount	\$ 95,000	\$ 225,030	\$ 320,030
Unamortized discount	(619)	(4,124)	(4,743)
Total unsecured convertible senior notes, net	\$ 94,381	\$ 220,906	\$ 315,287
Fair value of outstanding unsecured convertible senior notes (1)	<u>\$ 92,031</u>	<u>\$ 118,141</u>	

(1) The fair value is classified as Level 3 due to the limited trading activity for the unsecured convertible senior notes.

2023 Unsecured Convertible Senior Notes

Our 2023 Notes are unsecured and accrue interest at an annual rate of 6.25% per annum, payable semi-annually in arrears on May 15 and November 15 of each year. We expect to pay the \$95.0 million principal payment upon maturity on November 15, 2023 from our existing cash and investments on hand.

The unamortized debt issuance costs of \$0.1 million as of September 30, 2023 will be amortized to interest expense at an effective interest rate of 7.0% over the remaining term.

Subject to the satisfaction of certain conditions, 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), which equals approximately 4.9 million shares of common stock issuable upon conversion, 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 share price is trading between the initial conversion price of \$19.22 and \$28.84. However, should the market price of our common stock exceed the \$28.84 cap, then the conversion of the 2023 notes could have a dilutive impact or may require a cash expenditure to the extent the market price exceeds the cap price. As of September 30, 2023, approximately 4.9 million shares remained outstanding on the 2023 Capped Call and expire upon maturity of our 2023 Notes on November 15, 2023.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Contractual interest expense	\$ 1,484	\$ 1,484	\$ 4,453	\$ 4,453
Amortization of debt issuance costs	179	167	528	492
Total	<u>\$ 1,663</u>	<u>\$ 1,651</u>	<u>\$ 4,981</u>	<u>\$ 4,945</u>

2026 Unsecured Convertible Senior Notes

Our 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 unamortized debt issuance costs of \$3.2 million as of September 30, 2023 will be amortized to interest expense at an effective interest rate of 5.9% over the remaining term.

Subject to the satisfaction of certain conditions, the 2026 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 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 of common stock issuable upon conversion, subject to adjustment in certain circumstances.

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"), which cover the number of shares of our common stock underlying the 2026 Notes when our common stock share price is trading between the initial conversion price of \$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. As of September 30, 2023, approximately 12.2 million shares remained outstanding on the 2026 Capped Call.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Contractual interest expense	\$ 2,954	\$ 2,954	\$ 8,861	\$ 8,861
Amortization of debt issuance costs	312	294	922	869
Total	<u>\$ 3,266</u>	<u>\$ 3,248</u>	<u>\$ 9,783</u>	<u>\$ 9,730</u>

Future Minimum Principal Payments

Future minimum principal payments for the 2023 Notes and 2026 Notes as of September 30, 2023 are as follows (in thousands):

2023	\$ 95,000
2024	—
2025	—
2026	225,030
Total future minimum principal payments under the 2023 Notes and 2026 Notes	<u>\$ 320,030</u>

Note 8—OMIDRIA Royalty Obligation

On September 30, 2022, we sold to DRI an interest in our future OMIDRIA royalty receipts and received \$125.0 million in cash consideration which was recorded as an OMIDRIA royalty obligation on our condensed consolidated balance sheet. DRI is entitled to receive royalties on OMIDRIA net sales through December 31, 2030, subject to annual caps. DRI receives their prorated monthly cap amount before we receive any royalty proceeds. DRI is not entitled to carry-forward nor recoup any shortfall if the royalties paid by Rayner for an annual period are less than the cap amount applicable to each discrete calendar year. Additionally, DRI has no recourse to or security interest in our assets other than our OMIDRIA royalty receipts, and we retain all royalty receipts in excess of the respective cap in any given calendar year. At September 30, 2023, the maximum remaining amount that DRI is entitled to receive through the term of the agreement (December 31, 2030) is \$177.0 million, which, if fully paid, would be at an implied effective interest rate of 9.4% over the entire term of the agreement.

We consider our OMIDRIA royalty obligation to be a Level 3 obligation in the fair value hierarchy as its valuation relies on factors that are not easily observable in the market. As of September 30, 2023, the approximate fair value of our obligation was \$116.2 million.

For the three months and nine months ended September 30, 2023, we incurred cash interest expense of \$3.0 million and \$8.9 million, respectively.

As of September 30, 2023, the maximum scheduled principal and interest payments (based on an implied effective interest rate of 9.4%) are as follows:

	<u>Principal</u>	<u>Interest</u>	<u>Total Annual Cap</u>
	(In thousands)		
2023	\$ 298	\$ 2,952	\$ 3,250
2024	8,576	11,424	20,000
2025	14,641	10,359	25,000
2026	16,081	8,919	25,000
2027	17,664	7,336	25,000
Thereafter	68,164	10,586	78,750
Total scheduled payments	<u>\$ 125,424</u>	<u>\$ 51,576</u>	<u>\$ 177,000</u>

Note 9—Leases

We have an operating lease for our office and laboratory facilities with an initial term that ends in November 2027 and two options to extend the lease term by an additional five years each. Restricted investments of \$1.1 million represent the security deposit on our office and laboratory facilities. On January 14, 2022, we entered into an agreement with our landlord to early terminate a portion of the rentable square footage of our office and laboratory facilities, which reduced the right of use asset by \$4.7 million and related liability by \$5.2 million. We recorded a non-cash gain of \$0.5 million upon early termination of this portion of the lease. In addition, we carry various finance lease obligations for laboratory equipment.

Supplemental lease information is as follows:

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 30,</u>		<u>September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
	(In thousands)			
Lease cost				
Operating lease cost	\$ 1,603	\$ 1,659	\$ 4,852	\$ 4,529
Finance lease cost:				
Amortization	140	250	529	570
Interest	29	32	121	123
Variable lease cost	807	813	2,354	2,395
Sublease income	(375)	(432)	(1,125)	(1,377)
Net lease cost	<u>\$ 2,204</u>	<u>\$ 2,322</u>	<u>\$ 6,731</u>	<u>\$ 6,240</u>

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

	Nine Months Ended September 30,	
	2023	2022
	(In thousands)	
Cash paid for amounts included in the measurement of lease liabilities		
Cash payments for operating leases	\$ 5,356	\$ 5,312
Cash payments for financing leases	\$ 499	\$ 598

Note 10—Commitments and Contingencies

Good and Service Contracts

We have various agreements with third parties that collectively require payment of termination fees totaling \$27.4 million as of September 30, 2023 if we cancel the work within specific time frames, either prior to commencing or during performance of the contracted services.

Development Milestones and Product Royalties

We have licensed a variety of intellectual property from third parties that we are currently developing or may develop in the future. These licenses may require milestone payments during the clinical development processes or on approval of commercial sale as well as low single- to low double-digit royalties on the net income or net sales of the product. For the three and nine months ended September 30, 2023, we paid \$5.0 million associated with development milestone expenses related to the OMS906 program. For the three and nine months ended September 30, 2022, development milestones were not significant. Should narsoplimab be approved, we would owe milestone payments to development partners and would be obligated to pay low single-digit royalties on net sales of the product.

Note 11—Shareholders' Equity (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 September 30, 2023, we have not sold any shares under this program.

On April 12, 2023, warrants to purchase 200,000 shares of our common stock with an exercise price of \$23.00 per share expired without being exercised. We have no other warrants outstanding.

On November 9, 2023, the Board of Directors approved an indefinite term share repurchase program under which we may repurchase from time to time up to \$50.0 million of our common stock in the open market or through privately negotiated transactions.

Amendment of 2017 Omnibus Incentive Compensation Plan

At our June 23, 2023 annual meeting, our shareholders approved a 5,000,000 share increase in the number shares of common stock available for grant under the 2017 Omnibus Incentive Compensation Plan, as amended and restated. The total number of shares of common stock available for grant as of September 30, 2023 was 8,613,348.

Note 12—Stock-Based Compensation

Our stock option plans provide for the grant of incentive and non-qualified stock options, restricted stock awards, RSUs, and other stock awards to employees, non-employee directors and consultants.

Stock-based compensation is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Continuing operations				
Research and development	\$ 1,305	\$ 1,672	\$ 3,710	\$ 4,777
Selling, general and administrative	2,054	2,200	5,456	6,170
Total stock-based compensation in continuing operations	3,359	3,872	9,166	10,947
Discontinued operations				
Total stock-based compensation	\$ (124)	\$ (28)	\$ (207)	\$ (139)
	<u>\$ 3,235</u>	<u>\$ 3,844</u>	<u>\$ 8,959</u>	<u>\$ 10,808</u>

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

	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Estimated weighted-average fair value	\$ 2.42	\$ 2.54
Weighted-average assumptions:		
Expected volatility	93%	93%
Expected life, in years	7.1	7.1
Risk-free interest rate	3.98%	3.96%
Expected dividend yield	—%	—%

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

	Options	Weighted-Average Exercise Price per Share	Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2022	13,872,973	\$ 11.02		
Granted	2,908,200	3.13		
Exercised	(36,726)	4.10		
Forfeited	(1,439,517)	10.12		
Balance at September 30, 2023	<u>15,304,930</u>	<u>\$ 9.62</u>	<u>6.3</u>	<u>\$ 80</u>
Vested and expected to vest at September 30, 2023	<u>14,760,623</u>	<u>\$ 9.78</u>	<u>6.2</u>	<u>\$ 77</u>
Exercisable at September 30, 2023	<u>10,169,314</u>	<u>\$ 11.75</u>	<u>4.8</u>	<u>\$ 44</u>

Of the 15.3 million common stock options outstanding as of September 30, 2023, 15.2 million have an exercise price per share above \$ 2.92, which was the closing price of our stock on the Nasdaq exchange on September 30, 2023.

As of September 30, 2023, there were 5.1 million unvested options outstanding that will vest over a weighted-average period of 2.2 years. The total estimated compensation expense yet to be recognized on outstanding options is \$ 17.1 million.

The Company had 70,250 unvested RSUs outstanding as of September 30, 2023 that vest on December 1, 2023. The weighted average grant date fair value per share was \$7.53.

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

The following discussion and analysis of our financial condition and results of operations 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 and with our audited financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 13, 2023 and amended by Amendment No. 1 thereto, which was filed with the Securities and Exchange Commission (the "SEC") on May 1, 2023. In addition, you should read the section entitled "Risk Factors" and the disclaimers regarding forward-looking statements included herein and in our Annual Report on Form 10-K for the year ended December 31, 2022, for a discussion of important factors that could cause our results to differ materially from the results described in or implied by any forward-looking statements contained herein.

Overview

Omeros Corporation ("Omeros," the "Company" or "we") is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting immunologic diseases, including complement-mediated diseases and cancers related to dysfunction of the immune system, as well as addictive and compulsive disorders.

Complement Programs: Lectin Pathway / MASP-2

The lead drug candidate in our pipeline of complement-targeted therapeutics is narsoplimab (OMS721), a proprietary, patented human monoclonal antibody targeting mannan-binding lectin-associated serine protease 2 ("MASP-2"), the key activator of the lectin pathway of complement. Clinical development of narsoplimab is currently focused primarily on hematopoietic stem cell transplant-associated thrombotic microangiopathy ("HSCT-TMA").

We successfully completed a pivotal clinical trial for narsoplimab in HSCT-TMA and previously submitted to the U.S. Food and Drug Administration ("FDA") a biologics license application ("BLA") seeking marketing approval for narsoplimab in this indication. In late 2021, FDA issued a complete response letter ("CRL") with respect to the BLA in which the agency indicated that additional information would be needed to support regulatory approval. We appealed FDA's decision to issue the CRL through a formal dispute resolution process that concluded in late 2022. Although our appeal was denied, the decision identified potential paths for resubmission of the BLA based on both response data and survival data from the completed pivotal trial versus a historical control group, or based on survival data alone. Consistent with subsequent interactions with FDA's review division regarding resubmission of the BLA, we have submitted to FDA a formal analysis plan to assess already existing clinical trial data and certain existing external data, and we plan to include these analyses in a resubmitted BLA. We are currently awaiting FDA's feedback on the formal analysis plan and, assuming the agency's feedback is favorable, we intend to conduct the requisite analyses and, if results are positive, resubmit the BLA as expeditiously as possible. Assuming we reach agreement with FDA on our formal analysis plan in a single round of discussions then, allowing for FDA review time on a resubmitted BLA, we currently estimate that an approval decision on narsoplimab in HSCT-TMA could be rendered by FDA in mid-2024. There can be no guarantee that the specific requirements for resubmission, when determined through interaction with the FDA review division, will be satisfactory in terms of the time and/or expenditure required, that any new analyses conducted will result in favorable data, or that any resubmission of the BLA will result in approval of narsoplimab for HSCT-TMA.

In October 2023, we announced the result of the pre-specified interim analysis of our Phase 3 ARTEMIS-IGAN trial evaluating narsoplimab for the treatment of immunoglobulin A ("IgA") nephropathy. The primary endpoint is reduction in proteinuria assessed by 24-hour urine protein excretion ("UPE") at 36 weeks compared to placebo in the intent-to-treat population of 180 IgA nephropathy patients with high baseline proteinuria (24-hour UPE > 2 g/day). Topline results of the interim analysis showed that narsoplimab did not achieve statistically significant improvement over placebo on the proteinuria endpoint. The proteinuria reduction in the placebo group was markedly greater than that reported in Phase 3 clinical trials of other agents in IgA nephropathy. Based on the absence of statistical significance and as previously agreed with FDA, we determined not to submit an application for approval of narsoplimab in this indication and the ARTEMIS-IGAN clinical trial has been discontinued.

We are also developing OMS1029, a long-acting, next-generation antibody targeting MASP-2 and the lectin pathway. Dosing of all cohorts in a single-ascending dose Phase 1 clinical trial of OMS1029 was successfully completed in early 2023. OMS1029 was well tolerated with no safety concerns identified. Preliminary pharmacokinetic ("PK") and pharmacodynamic ("PD") data show dose-proportional exposure and sustained lectin pathway inhibition, consistent with potentially quarterly intravenous or subcutaneous dosing. Dosing has been completed in the first cohort of our ongoing Phase 1 multiple-ascending-dose study of OMS1029 in healthy subjects. A Phase 2 program is expected to begin in mid-2024.

Complement Programs: Alternative Pathway / MASP-3

Our pipeline of clinical-stage complement-targeted therapeutic candidates also includes OMS906, a proprietary, patented monoclonal antibody targeting mannan-binding lectin-associated serine protease 3 (“MASP-3”), the key activator of the alternative pathway of complement. We believe OMS906 has the potential to treat a wide range of alternative pathway-related diseases and that its attributes favorably differentiate OMS906 from other marketed and in-development alternative pathway inhibitors. Clinical development of OMS906 is currently ongoing in multiple alternative pathway-related disorders, including complement 3 glomerulopathy (“C3G”), a rare chronic kidney disease, and paroxysmal nocturnal hemoglobinuria (“PNH”), a rare and life-threatening hemolytic blood disorder.

In June 2023, results from a pre-specified interim analysis of our ongoing clinical trial of OMS906 in complement-inhibitor-naïve adults with PNH were presented at the 2023 congress of the European Hematology Association and updated interim analysis data from this study are scheduled for podium presentation at the 2023 annual meeting of the American Society of Hematology in December. Both presentations report statistically significant and clinically meaningful improvements in all measured markers of hemolysis, including hemoglobin and lactate dehydrogenase. No patients were reported to have had a clinical breakthrough of PNH or a thrombotic event, and none were reported to require a transfusion while receiving OMS906 treatment. Enrollment is now complete and dosing is ongoing in our Phase 2 clinical trial evaluating OMS906 in PNH patients who have had an unsatisfactory response to the C5 inhibitor ravulizumab. We are initiating an open-label extension study to assess the long-term efficacy and safety of OMS906 in patients with PNH. In the extension study, patients who have completed a previous PNH study evaluating OMS906 will roll directly into the extension study without a break in OMS906 treatment. Data from this study will contribute to a planned BLA for OMS906 in the treatment of PNH. Based on PK data from a successful Phase 1 single-ascending-dose study of OMS906 in healthy subjects and interim data from our ongoing clinical trials in PNH patients, we are expecting a dosing frequency of once quarterly for the Phase 3 studies and commercialization.

Enrollment in our Phase 2 clinical program evaluating OMS906 in patients with C3G is also ongoing. Initiation of Phase 3 clinical programs for OMS906 in PNH and C3G are targeted for the third quarter of 2024.

PDE7 Inhibitor Program

Our development pipeline also includes OMS527, our phosphodiesterase 7 (“PDE7”) inhibitor program focused on addiction and movement disorders. In April 2023, we were awarded a grant from the National Institute on Drug Abuse, part of the National Institutes of Health, to develop our lead orally administered PDE7 inhibitor compound, for which we have successfully completed a Phase 1 study, for the treatment of cocaine use disorder (“CUD”). The grant amount, a total of \$6.69 million over three years, is intended to support preclinical cocaine interaction/toxicology studies to assess safety of the therapeutic candidate in the presence of concomitant cocaine administration, as well as an in-patient, placebo-controlled clinical study evaluating the safety and effectiveness of OMS527 in adults with CUD who receive concurrent intravenous cocaine. We expect the preclinical studies to begin in early 2024. Additionally, with investigators at Emory University, we are also evaluating OMS527 as a potential treatment for levodopa-induced dyskinesias, a common and debilitating side effect of long-term levodopa dosing in patients with Parkinson’s disease.

Pre-clinical Programs

We also have a diverse group of preclinical programs, including five immuno-oncology platforms directed to development of novel adoptive T cell/CAR-T therapies and novel immunotherapeutics and cancer vaccines.

OMIDRIA

We previously developed and commercialized OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%, which is approved by FDA for use during cataract surgery or intraocular lens (“IOL”) replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. We marketed OMIDRIA in the United States (the “U.S.”) from the time of its commercial launch in 2015 until December 2021.

On December 23, 2021, we sold our commercial product OMIDRIA and certain related assets, including inventory and prepaid expenses to Rayner Surgical Inc. ("Rayner"). Rayner paid us \$126.0 million in cash at the closing and we retained all outstanding accounts receivable, accounts payable, and accrued expenses as of the closing date.

Under the Asset Purchase Agreement with Rayner (the "Asset Purchase Agreement"), we were entitled to receive a milestone payment of \$200.0 million (the "Milestone Payment") within 30 days following an event (the "Milestone Event") that establishes separate payment for OMIDRIA for a continuous period of at least four years when furnished in the ambulatory surgery center ("ASC") setting. The Milestone Event occurred in December 2022 and we recorded a \$200.0 million milestone receivable. We received the Milestone Payment together with accrued interest in February 2023.

Under the Asset Purchase Agreement, the occurrence of the Milestone Event in December 2022 triggered a reduction in the U.S. royalty rate from 50% to 30% on OMIDRIA net sales until the expiration or termination of the last issued and unexpired U.S. patent, which we expect to occur no earlier than 2033. Upon the occurrence of certain events described in the Asset Purchase Agreement, including during any specific period in which OMIDRIA is no longer eligible for separate payment (i.e., included in the packaged payment rate for the surgical procedure) under Medicare Part B, the U.S. base royalty rate would be reduced to 10%. Pursuant to legislation enacted in late 2022, we expect separate payment for OMIDRIA under Medicare Part B to extend until at least January 1, 2028.

On September 30, 2022, we sold to DRI Healthcare Acquisitions LP ("DRI") an interest in a portion of our future OMIDRIA royalty receipts and received \$125.0 million in cash consideration, which we recorded as a liability on our condensed consolidated balance sheet. The liability is being amortized over the term of the arrangement using the implied effective interest rate of 9.4%. Interest expense is recorded as a component of continuing operations. As of September 30, 2023, the maximum future payout that DRI is entitled to receive through the remaining term of the agreement is \$177.0 million. The term of the agreement with DRI runs through December 31, 2030, and our payments to DRI will not total \$125.0 million until August 2028 at the earliest.

Financial Summary

Our loss for the three and nine months ended September 30, 2023 was \$37.8 million and \$108.7 million, respectively. As of September 30, 2023, we had cash, cash equivalents and short-term investments of \$310.3 million available to fund operations and debt service. On November 15, 2023, we have a \$95.0 million principal payment due at maturity on our 2023 unsecured convertible senior notes (the "2023 Notes") which we expect to pay at maturity from our existing cash and investments on hand. Our cash provided by operations for the nine months ended September 30, 2023 was \$109.6 million which includes the collection of our \$200.0 million Milestone Payment.

Results of Operations

Research and Development Expenses

Our research and development expenses can be divided into three categories: direct external expenses, which include clinical research and development and preclinical research and development activities; internal, overhead and other expenses; and stock-based compensation expense. Direct external expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations prior to receiving regulatory approval for a drug candidate, contract research organizations (“CROs”), clinical trial sites, collaborators, and licensors and consultants. Pre-clinical research and development includes costs prior to beginning Phase 1 studies in human subjects. Internal, overhead and other expenses primarily consist of costs for personnel, overhead, rent, utilities and depreciation. The following table illustrates our expenses associated with these activities:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Research and development expenses:				
Direct external expenses:				
Clinical research and development:				
MASP-2 program - OMS721 (narsoplimab)	\$ 8,643	\$ 23,097	\$ 27,566	\$ 40,839
MASP-3 program - OMS906	9,246	2,015	17,037	3,997
MASP-2 program - OMS1029	1,108	1,502	3,818	1,502
Other	46	171	122	389
Total clinical research and development	19,043	26,785	48,543	46,727
Preclinical research and development	1,046	1,125	3,488	6,374
Total direct external expenses	20,089	27,910	52,031	53,101
Internal overhead and other expenses	10,337	8,986	30,239	28,294
Stock-based compensation expenses	1,305	1,672	3,710	4,777
Total research and development expenses	<u>\$ 31,731</u>	<u>\$ 38,568</u>	<u>\$ 85,980</u>	<u>\$ 86,172</u>

For the three months ended September 30, 2023, clinical research and development expenses decreased \$7.7 million compared to the prior year quarter due primarily to decreased narsoplimab clinical manufacturing in the current year quarter. This decrease was partially offset by a \$5.0 million payment made to a third-party licensor in connection with achievement of a development milestone in our OMS906 program, as well as increasing drug manufacturing costs to support our OMS906 clinical trials.

Clinical research and development expenses for the nine months ended September 30, 2023 increased \$1.8 million compared to the same period in the prior year primarily due to the \$5.0 million OMS906 development milestone and the transition of OMS1029 from preclinical to clinical research and development upon the initiation of human trials. This was partially offset by decreased narsoplimab clinical manufacturing costs during the current year period.

Preclinical research and development expenses decreased \$0.1 million and \$2.9 million for the three and nine months ended September 30, 2023, respectively, as compared to the same periods in 2022, due primarily to the transitioning of OMS1029 from preclinical research and development to clinical research and development during the third quarter of 2022.

Internal overhead and other expenses increased \$1.4 million and \$1.9 million for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022, due to additional employee-related costs. The increase over the nine-month periods was partially offset by the recognition of an employee retention tax credit from the Internal Revenue Service in the first quarter of 2023.

The \$0.4 million and \$1.1 million decreases in stock-based compensation expenses for the three and nine months ended September 30, 2023, respectively, as compared to the same periods in the prior year were primarily due to the valuation and timing of the vesting of employee stock options.

During the fourth quarter, we will incur various costs associated with the termination of the ARTEMIS-IGAN trial. We expect research and development expenses in the fourth quarter of 2023 to be similar to the third quarter of this year.

At this time, we are unable to estimate with certainty the longer-term costs we will incur in the continued development of our drug candidates due to the inherently unpredictable nature of our preclinical and clinical development activities. Clinical development timelines, the probability of success and development costs can change 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 drug candidate as well as ongoing assessments of each program's commercial potential. In addition, we cannot forecast with precision which drug 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 drug candidates due to the lengthy process of completing clinical trials and seeking regulatory approval. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could delay our generation of product revenue and increase our research and development expenses.

Selling, General and Administrative Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Selling, general and administrative expenses:				
Selling, general and administrative expenses, excluding stock-based compensation expense	\$ 14,368	\$ 9,998	\$ 33,329	\$ 30,909
Stock-based compensation expense	2,054	2,200	5,456	6,170
Total selling, general and administrative expenses	\$ 16,422	\$ 12,198	\$ 38,785	\$ 37,079

For the three months ended September 30, 2023, selling, general and administrative costs excluding stock-based compensation expense increased \$4.4 million compared to the prior year quarter primarily due to a non-recurring employee compensation expense.

For the nine months ended September 30, 2023, selling, general and administrative costs excluding stock-based compensation expense, increased \$2.4 million compared to the prior year period due primarily to a non-recurring employee compensation expense, partially offset by both an employee retention tax credit taken in the first quarter related to the CARES Act and decreased patent and marketing costs associated with our HSCT-TMA program.

The \$0.1 million and \$0.7 million decreases in stock-based compensation expense for the three and nine months ended September 30, 2023 compared to the same periods in the prior year were primarily due to the valuation and timing of the vesting of employee stock options.

We expect selling, general and administrative expenses in the fourth quarter of 2023 to return to historical levels.

Interest Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Interest expense	\$ 7,916	\$ 4,932	\$ 23,781	\$ 14,799

Interest expense is primarily comprised of interest and amortization of debt discount and issuance costs related to our unsecured convertible senior notes and interest on our DRI royalty obligation (see “Note 7 - Unsecured Convertible Senior Notes” and “Note 8 – OMIDRIA Royalty Obligation” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q). The \$3.0 million and \$9.0 million increases in interest expense between the three and nine months ended September 30, 2023 and 2022 were primarily due to interest expense on our OMIDRIA royalty obligation, which we entered in September 2022.

We expect that interest expense for the fourth quarter of 2023 to be lower than the third quarter of this year due to the repayment at maturity of our \$95.0 million of outstanding 2023 Notes on November 15, 2023.

Interest and Other Income

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Interest and other income	\$ 4,413	\$ 906	\$ 12,913	\$ 2,069

Interest and other income increased \$3.5 million and \$10.8 million for the three and nine months ended September 30, 2023, respectively, as compared to the same periods in 2022, due to holding higher average cash and investment balances than in the prior year as a result of receiving a \$200.0 million Milestone Payment from Rayner in February 2023.

We expect interest and other income for the fourth quarter of 2023 to be less than the third quarter of this year due to a reduction in our overall cash and investments available to invest upon the repayment at maturity of the \$95 million outstanding principal on our 2023 Notes.

Discontinued operations and OMIDRIA contract royalty asset

Net income from OMIDRIA discontinued operations, net of tax is shown below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands)			
Interest earned on OMIDRIA contract royalty asset	\$ 3,730	\$ 4,356	\$ 11,484	\$ 13,739
Remeasurement adjustments	10,100	32,917	14,924	40,631
Other income, net	76	63	480	295
Net income from discontinued operations, net of tax	<u>\$ 13,906</u>	<u>\$ 37,336</u>	<u>\$ 26,888</u>	<u>\$ 54,665</u>

Interest is earned on the OMIDRIA contract royalty asset at an implied effective interest rate of 11.0%. The \$0.6 million and \$2.3 million reductions in interest earned for the three and nine months ended September 30, 2023 as compared to the same periods in 2022 were due to a decrease in the balance of the OMIDRIA contract royalty asset during the respective periods.

The remeasurement adjustments for the three and nine months ended September 30, 2023 decreased by \$22.8 million and \$25.7 million, respectively, as compared to the corresponding prior year periods. The primary reason for the decrease was due to adjusting the OMIDRIA contract royalty asset in the third quarter of 2022 to reflect an increase in expected future OMIDRIA royalties based on actual sales results.

The following schedule presents a roll forward of the OMIDRIA contract royalty asset (in thousands):

OMIDRIA contract royalty asset at December 31, 2022	\$	152,222
Royalties earned		(29,900)
Interest earned on OMIDRIA contract royalty asset		11,484
Remeasurement adjustments		14,924
OMIDRIA contract royalty asset at September 30, 2023	\$	<u>148,730</u>

The occurrence of the Milestone Event in December 2022 triggered a reduction in the royalty rate applicable to U.S. net sales of OMIDRIA from 50% to 30%.

Financial Condition - Liquidity and Capital Resources

As of September 30, 2023, we had cash, cash equivalents and short-term investments of \$310.3 million. Our loss for the three and nine months ended September 30, 2023 was \$37.8 million and \$108.7 million, respectively, and our cash provided by operations for the nine months ended September 30, 2023 was \$109.6 million. Cash provided by operations includes collection of the \$200.0 million Milestone Payment.

We have \$95.0 million principal outstanding related to the 2023 Notes which mature and become due on November 15, 2023. We plan to repay the 2023 Notes from our existing cash and investments on hand. From time to time, we may repurchase our outstanding 2026 Notes in the open market or through privately negotiated transactions. In addition, on November 9, 2023, the Board of Directors approved an indefinite term share repurchase program under which we may repurchase from time to time up to \$50.0 million of our common stock in the open market or through privately negotiated transactions.

Historically, we have incurred net losses from continuing operations and negative operating cash flows. We have not yet established an ongoing source of revenue sufficient to cover our operating costs; therefore, we would need to continue to raise additional capital to accomplish our business plan and to retire our outstanding convertible senior notes due in 2026. We plan to continue to fund our operations for at least the next twelve months with our existing cash, investments and royalties from Rayner. We have a sales agreement in place for an “at the market” equity offering facility through which we may offer and sell shares of our common stock equaling an aggregate amount up to \$150.0 million. Should it be determined to be strategically advantageous, we could also 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 technologies. Should it be necessary to manage our operating expenses, we could also reduce our projected cash requirements by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

Cash Flow Data

	Nine Months Ended September 30,	
	2023	2022
(In thousands)		
Selected cash flow data		
Cash provided by (used in):		
Operating activities	\$ 109,551	\$ (61,101)
Investing activities	\$ (88,789)	\$ (19,073)
Financing activities	\$ (1,131)	\$ 124,899

Operating Activities. Net cash provided by operating activities for the nine months ended September 30, 2023 increased by \$170.7 million as compared to the same period in 2022. The increase was primarily due to a \$182.0 million decrease in receivables due to the collection of our \$200.0 million Milestone Payment and a \$15.3 million change in accounts payable, accrued expenses and other. This was offset by a \$27.4 million increase in net loss, a \$17.7 million change in OMIDRIA Rayner royalties receivables and \$19.3 million of non-cash charges.

Investing Activities. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and proceeds from the sale of short-term investments, thus causing a shift between our cash and cash equivalents and short-term investment balances. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider fluctuations in cash flows from investing activities to be important to the understanding of our liquidity and capital resources.

Net cash used in investing activities for the nine months ended September 30, 2023 increased \$69.7 million compared to the prior year period, due to net purchases of short-term investments outweighing proceeds from sales and maturities. Investment activities during 2023 included receipt and investing of the \$200.0 million Milestone Payment from Rayner and the \$125.0 million we received from DRI related to the sale of a portion of our future OMIDRIA royalties. In the prior year period, net purchases of short-term investments included investing the proceeds from the sale of OMIDRIA to Rayner.

Financing Activities. Net cash used in financing activities during the nine months ended September 30, 2023 increased \$126.0 million compared to the same period in 2022. This was primarily due to the \$125.0 million we received from DRI related to the sale of a portion of our future OMIDRIA royalties in September 2022.

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, 2022. Other than the following, our future minimum contractual obligations and commitments have not changed materially from the amounts previously reported. See “Note 10 – Commitments and Contingencies” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q.

Operating Leases

Our lease for our office and laboratory space ends in November 2027. We have two options to extend the lease term by five years each. In addition, we carry various finance lease obligations for laboratory equipment. As of September 30, 2023, the remaining aggregate non-cancelable rent payable under the initial term of the lease, excluding common area maintenance and related operating expenses, is \$28.6 million.

Convertible Notes

See “Note 7 – Unsecured Convertible Senior Notes” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q.

OMIDRIA Royalty Obligation

See “Note 8 – OMIDRIA Royalty Obligation” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q.

Goods and Services Contracts, Development Milestones and Product Royalties

See “Note 10 – Commitment and Contingencies” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q.

Critical Accounting Policies and Significant Judgments and Estimates

There have not been any material changes in our critical accounting policies and significant judgments and estimates as disclosed in Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 13, 2023.

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, and we do not enter into financial instruments for trading or speculative purposes. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities. As of September 30, 2023, we had cash, cash equivalents and short-term investments of \$310.3 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 September 30, 2023. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2023, 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, 2022, as filed with the SEC on March 13, 2023. In assessing the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2022, 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 to be immaterial or by other risks that are not currently known to us. Due to these risks and uncertainties, known and unknown, our past financial results may not be a reliable indicator of future performance and historical trends should not be used to anticipate results or trends in future periods. 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

On November 9, 2023, the Board of Directors approved an indefinite term share repurchase program under which we may repurchase from time to time up to \$50.0 million of our common stock in the open market or through privately negotiated transactions.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

Exhibit Number	Description
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Link base Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104.1	Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101)

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

SIGNATURES

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

OMEROS CORPORATION

Dated: November 9, 2023

/s/ Gregory A. Demopoulos

Gregory A. Demopoulos, M.D.

President, Chief Executive Officer and Chairman of the Board of Directors

Dated: November 9, 2023

/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. Demopulos, M.D., certify that:

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

Dated: November 9, 2023

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

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

I, Michael A. Jacobsen, certify that:

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

Dated: November 9, 2023

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS
ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Omeros Corporation (the “Company”) for the quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

Dated: November 9, 2023

/s/ Gregory A. Demopulos

Gregory A. Demopulos, M.D.

Principal Executive Officer

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS
ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Omeros Corporation (the “Company”) for the quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

Dated: November 9, 2023

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer