UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 9, 2023

OMEROS CORPORATION
(Exact name of Registrant as Specified in Its Charter)

Washington	**001-34475**	**91-1663741**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
201 Elliott Avenue West Seattle, WA		**98119**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (206) 676-5000

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities Registered Pursuant to Section 12(b) of the Act:

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2023, Omeros Corporation issued a press release announcing financial results for the three months ended March 31, 2023. A copy of such press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the United States Securities and Exchange Commission made by Omeros Corporation, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release, dated May 9, 2023, pertaining to Omeros Corporation's financial results for the three months ended March 31, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

OMEROS CORPORATION

Date: May 9, 2023

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

Omeros Corporation Reports First Quarter 2023 Financial Results

– Conference Call Today at 4:30 p.m. ET –

SEATTLE, WA – May 9, 2023 – Omeros Corporation (Nasdaq: OMER), a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders including complement-mediated diseases, cancers, and addictive and compulsive disorders, today announced recent highlights and developments as well as financial results for the first quarter ended March 31, 2023, which include:

- Net loss was $33.7 million in the first quarter of 2023, or $0.54 per share, compared to a net loss in the first quarter of 2022 of $33.0 million, or $0.53 per share; our first quarter's net loss from continuing operations was $39.7 million compared to $39.5 million in the first quarter of 2022, and $0.63 per share for both periods. Cash burn for the first quarter of 2023 was $23.6 million, exclusive of a $200 million milestone payment received in the quarter, a decrease from $26.0 million in the prior quarter.

- In February 2023 we received from Rayner Surgical, Inc. ("Rayner") the $200 million milestone payment due under the Asset Purchase Agreement by which we sold our former ophthalmology product OMIDRIA® to Rayner in late 2021. The payment became due upon the achievement of the milestone event in December 2022 and was recorded as a receivable in the fourth quarter of 2022.

- For the quarter ended March 31, 2023, we earned OMIDRIA royalties of $9.2 million on Rayner's U.S. net sales of $30.7 million. This compares to earned royalties of $13.8 million during the first quarter of the prior year on U.S. net sales of $27.7 million. The above-referenced milestone event triggered a reduction of our U.S. base royalty rate from 50 percent to 30 percent.

- At March 31, 2023, we had $371.4 million of cash, cash equivalents and short-term investments available. In addition, we had $10.0 million of accounts receivable.

- We intend to resubmit our Biologics License Application ("BLA") for narsoplimab in hematopoietic stem cell transplant-associated thrombotic microangiopathy ("TA-TMA") and, consistent with direction from FDA's Office of New Drugs, have submitted to FDA a proposed plan for assessment of both response rate and survival based on already existing clinical trial data and external data. A meeting with the review division is scheduled for this month to discuss the details of our proposed analyses and to confirm the information required by FDA to support resubmission of the BLA for narsoplimab's approval.

- In April 2023, we announced positive results from a pre-specified interim analysis of our ongoing Phase 1b clinical trial of OMS906 in treatment-naïve adults with paroxysmal nocturnal hemoglobinuria ("PNH"), and updated interim results are provided later in this release.

- In April 2023, we were awarded a three-year $6.69 million grant from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health, to develop the lead orally administered PDE7 inhibitor compound in our OMS527 program for the treatment of cocaine use disorder ("CUD").

"We are pleased with our progress during the first quarter as our team continues to deliver on important milestones," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "For our MASP-2 inhibitor narsoplimab, we are meeting with FDA this month to discuss our proposed analysis plan and confirm the specifics to be included in a BLA

resubmission for TA-TMA, and our Phase 3 IgA nephropathy trial remains on track for data read-out next quarter. Our long-acting MASP-2 inhibitor is set to begin enrolling its multiple-ascending-dose clinical trial this summer in the U.S. Enrollment is marching ahead in our OMS906 clinical program. The results to date in treatment-naïve PNH patients are impressive, making clear that our MASP-3 inhibitor OMS906 blocks alternative pathway activation and should be effective across AP-related diseases while potentially offering significant safety, efficacy and compliance advantages over other AP-targeting drugs. Now collaborating with and having received a $6.69 million award from NIDA, we are moving forward to assess our PDE7 inhibitor OMS527 in patients with cocaine use disorder. Our immuno-oncology franchise is also rapidly progressing across both our cellular and biologic platforms. Helping to fund the ongoing achievements of these and our other programs is the non-dilutive $200 million milestone payment received in February, forecast to extend our cash runway into 2025. This year has started well for Omeros, and we expect that momentum to continue."

First Quarter and Recent Clinical Developments

- Recent developments regarding narsoplimab, our lead monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 ("MASP-2") in advanced clinical programs for the treatment of TA-TMA and immunoglobulin A ("IgA") nephropathy, include:

    - We are preparing to meet with FDA's Division of Nonmalignant Hematology later this month to confirm the information required by FDA to support resubmission of the BLA for narsoplimab's approval in TA-TMA. Consistent with direction from FDA's Office of New Drugs, provided as part of its denial of our appeal of the complete response letter previously issued by FDA, we have proposed a plan to assess already existing clinical trial data and external data on both response rate and survival.

    - In our Phase 3 ARTEMIS-IGAN trial evaluating narsoplimab for the treatment of IgA nephropathy, we remain on track to read out 9-month data on the proteinuria endpoint next quarter.

    - Narsoplimab is the focus of two recent peer-reviewed publications. One, in *Thrombosis Journal*, describes a 6-year-old girl with TA-TMA following stem cell transplantation for severe aplastic anemia who had failed treatment with defibrotide. Treated with narsoplimab under compassionate use, her TMA resolved. A recurrence of TMA triggered by parvovirus again was successfully treated with narsoplimab. A second manuscript authored by investigators at Weill Cornell Medicine is in press at *Clinical and Experimental Immunology*. The manuscript reports a high correlation between elevation of a biomarker of endothelial injury and TA-TMA. Using plasma samples from patients in the narsoplimab pivotal trial, the study also showed that, in those trial patients classified as "responders," narsoplimab restored biomarker levels to those of stem-cell transplant patients without TMA while biomarker levels in narsoplimab "non-responders" remained high.

    - The 49th annual meeting of the European Society for Blood and Marrow Transplantation (EBMT), which recently concluded in Paris, featured three presentations regarding narsoplimab in TA-TMA. The first described the design of our ongoing multi-center Phase 2 study evaluating the efficacy and safety of narsoplimab in high-risk pediatric patients with TA-TMA. The second was a case report of a patient treated with narsoplimab under our compassionate use program. The patient had worsening TA-TMA following withdrawal of calcineurin inhibitors, which resolved following narsoplimab treatment. The third was a report of five cases of high-risk pediatric TA-TMA. Three of five failed treatment with the C5 inhibitor eculizumab. Two of these three patients also failed treatment with defibrotide and were then treated with narsoplimab, provided under compassionate use. Following narsoplimab treatment, TA-TMA resolved.

    - At the annual meeting of the American Society of Pediatric Hematology/Oncology, being held this week in Fort Worth, Texas, clinical investigators will present the course of a 3-year-old girl with relapsed high-risk neuroblastoma who developed refractory TA-TMA following a second stem cell transplant. After failing treatment with each of eculizumab and defibrotide, the patient's TA-TMA resolved following treatment with narsoplimab.

- A case report on narsoplimab treatment of a patient with recurrent IgA nephropathy was featured at the recent annual meeting of the Korean Society of Nephrology. Treatment with narsoplimab stabilized both proteinuria and estimated glomerular filtration rate ("eGFR"). Kidney biopsy results confirmed the beneficial effects of narsoplimab in this patient. This was the first report of complement inhibitor treatment of a patient with recurrent IgA nephropathy.

- A manuscript authored by a group of international experts detailing the role of the lectin pathway in the pathophysiology of IgA nephropathy, including glomerular injury, thrombotic microangiopathy, and tubulointerstitial fibrosis, was recently accepted for publication in *Kidney International*.

- Recent developments regarding OMS1029, our long-acting, next-generation MASP-2 inhibitor, include:

  - In April 2023, we announced results from a pre-specified interim analysis of our ongoing Phase 1b clinical trial of OMS906 in treatment-naïve adults with PNH. Updated data from this open label trial continue to show statistically significant and clinically meaningful improvements in all measured markers of hemolysis, including hemoglobin ("Hgb") and lactate dehydrogenase ("LDH"). Despite all patients having received only the lowest of doses planned for the trial, data compare very favorably to those publicly available for marketed and in-development alternative pathway inhibitors. Enrollment is ongoing. Updated data are provided below ("n", or the number of patients, at each time point ranges from 3 to 9 depending on each patient's respective date of enrollment):

    Hemoglobin
    - Mean baseline Hgb is 6.78 g/dL (normal: 12.0–15.6 g/dL for women, 13.5–17.2 g/dL for men)
    - Mean absolute increase in Hgb is 3.4 g/dL at Day 29, 6.3 g/dL at Day 85, and 9.7 g/dL at Day 113
    - After only 1 dose (by Day 29), Hgb increased ≥ 2 g/dL in 67% of patients
    - After only 2 doses (by Day 57), Hgb increased ≥ 2g/dL in 100% and by ≥ 4 g/dL in 80% of patients
    - By Day 85, 67% of patients had Hgb ≥ 12 g/dL; by Day 113, 100% of patients had Hgb ≥ 15.7 g/dL
    - Mean reduction in absolute reticulocyte counts from baseline were ≥ 70,000/µL (range 70,000 – 136,000/µL) at all time points
    - No patients have had a clinical breakthrough or thrombotic event, and none have required a transfusion while receiving OMS906

    LDH
    - Mean baseline LDH is 1931 U/L (~8-fold higher than the upper limit of normal)
    - Mean reduction in LDH is 83% at Day 15, 80% at Day 29, and 87% at Day 113
    - At Day 113, LDH for all patients is normal or < 1.5 times normal

    Both Hgb and LDH improvements are statistically significant at all time points in the trial; OMS906 has been well tolerated and there have been no safety signals of concern.

  - Based on PK/PD data from a successful Phase 1 single-ascending-dose study of OMS906 in healthy subjects and the interim data from our Phase 1b clinical trial in treatment-naïve PNH patients, we are planning a dosing frequency of once quarterly, either intravenously or subcutaneously.

  - We are also enrolling a Phase 1b clinical trial evaluating OMS906 in PNH patients who have had an unsatisfactory response to the C5 inhibitor ravulizumab. This study has a "switch-over" design and enrolls PNH patients receiving ravulizumab, adds OMS906 to provide combination therapy with ravulizumab for 24 weeks, and then provides OMS906 monotherapy in patients who demonstrate a hemoglobin response with combination therapy. Patient treatment with OMS906 is underway.

  - A Phase 1b clinical program evaluating OMS906 in patients with complement 3 glomerulopathy ("C3G") is also ongoing.

  - Additional updates on data from our three OMS906 trials in progress are planned for the second half of this year.

- The Annual Meeting of the European Hematology Association to be held this June in Frankfurt, Germany, will feature a presentation on the study design of our two ongoing clinical trials of OMS906 in patients with PNH, along with results from our single-ascending-dose Phase 1 study evaluating both intravenous and subcutaneous administration of OMS906 in healthy subjects.

- Recent developments regarding OMS527, our phosphodiesterase 7 ("PDE7") inhibitor program focused on addiction and movement disorders, include:

  - 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 the treatment of cocaine use disorder ("CUD"). The grant – $6.69 million over three years – is intended to support a preclinical cocaine interaction study and a randomized, placebo-controlled, inpatient clinical study evaluating the safety and effectiveness of OMS527 in patients with CUD. A Phase 1 clinical trial of the study drug in healthy subjects was successfully completed.

  - OMS527 is also being evaluated by investigators at Emory University as a potential treatment for levodopa-induced dyskinesias ("LID"), which are crippling, involuntary movements reportedly affecting 50 percent or more of levodopa-treated patients with Parkinson's disease. LID is caused by prolonged treatment with levodopa, the most prescribed treatment for the over 10 million patients with Parkinson's disease worldwide. Data on OMS527 in LID will be publicly disclosed following the filing of appropriate patent applications.

Financial Results

Net loss for the first quarter of 2023 was $33.7 million, or $0.54 per share. This compares to a net loss in the first quarter of 2022 of $33.0 million, or $0.53 per share. Net loss from continuing operations for the first quarter of 2023 was $39.7 million compared to $39.5 million in the first quarter of 2022, and $0.63 per share for both periods. Cash burn for the first quarter of 2023 was $23.6 million, exclusive of the $200 million milestone payment from Rayner, compared to $26.0 million in the fourth quarter of 2022.

During the first quarter of 2023, we earned royalties of $9.2 million on $30.7 million of Rayner's U.S. net sales of OMIDRIA. This compares to earned royalties of $13.8 million during the first quarter of the prior year on U.S. net sales of $27.7 million. These royalties were recorded as a reduction of the OMIDRIA contract royalty asset. Omeros received a $200 million milestone payment from Rayner in the first quarter of 2023 in connection with the Asset Purchase Agreement under which Rayner purchased our OMIDRIA business. The achievement of the milestone event in late December 2022 triggered a reduction of our U.S. base royalty rate from 50 percent to 30 percent.

Total costs and expenses for the first quarter of 2023 were $35.7 million compared to $35.0 million for the first quarter of 2022.

Interest expense during the first quarter of 2023 was $7.9 million compared to $4.9 million during the first quarter of 2022. The increase was due to interest on our OMIDRIA contract royalty obligation associated with the sale of a portion of our OMIDRIA royalty receivables, which we entered into during the third quarter of 2022.

During the first quarter of 2023, we earned $4.0 million in interest and other income compared to $0.5 million in the prior year quarter. The increase was due to higher average balances available to invest and higher market interest rates in the current year quarter.

Net income from discontinued operations, net of tax was $6.0 million, or $0.09 per share, in the first quarter of 2023 compared to $6.5 million, or $0.10 per share, in the first quarter of 2022.

As of March 31, 2023, we had $371.4 million of cash and short-term investments, all of which are held in our name, available for operations and debt service. In addition, we had $10.0 million in accounts receivable. Our cash provided by operations during the first quarter of 2023 was $174.5 million and included the $200.0 million collection of the Rayner milestone payment.

Conference Call Details

To access the live conference call via phone, please dial (800) 715-9871 from the United States and Canada or (646) 307-1963 internationally and ask to be placed into the Omeros earnings call. Please dial in approximately 10 minutes prior to the start of the call. A telephone replay will be available for one week following the call and may be accessed by dialing (800) 770-2030 from the United States or Canada or (609) 800-9909 internationally. The replay access code is 8266699.

For online access to the live or subsequently archived webcast of the conference call, go to Omeros' website at https://investor.omeros.com/upcoming-events.

About Omeros Corporation

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders including complement-mediated diseases, cancers, and addictive and compulsive disorders. Omeros' lead MASP-2 inhibitor narsoplimab targets the lectin pathway of complement and is the subject of a biologics license application pending before FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA). Narsoplimab is also in multiple late-stage clinical development programs focused on other complement-mediated disorders, including IgA nephropathy, COVID-19, and atypical hemolytic uremic syndrome. Omeros' long-acting MASP-2 inhibitor OMS1029 is currently in a Phase 1 clinical trial. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is advancing across multiple clinical programs for alternative pathway-related diseases, including paroxysmal nocturnal hemoglobinuria (PNH) and complement 3 (C3) glomerulopathy. For more information about Omeros and its programs, visit www.omeros.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are subject to the "safe harbor" created by those sections for such statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "likely," "look forward to," "may," "objective," "plan," "potential," "predict," "project," "should," "slate," "target," "will," "would" and similar expressions and variations thereof. Forward-looking statements, including statements regarding prospects for obtaining FDA approval of narsoplimab in TA-TMA and anticipated next steps in relation to the biologics license application for narsoplimab, expectations regarding the initiation or continuation of clinical trials evaluating Omeros' drug candidates and the anticipated availability of data therefrom, and expectations regarding growth in royalty-generating sales of OMIDRIA, are based on management's beliefs and assumptions and on information available to management only as of the date of this press release. Omeros' actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, unanticipated or unexpected outcomes of regulatory processes in relevant jurisdictions, unproven preclinical and clinical development activities, financial condition and results of operations, regulatory processes and oversight, challenges associated with manufacture or supply of our investigational or clinical products, changes in reimbursement and payment policies by government and commercial payers or the application of such policies, intellectual property claims, competitive developments, litigation, and the risks, uncertainties and other factors described under the heading "Risk Factors" in the company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2023. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and the company assumes no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Contact:

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OMEROS CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Costs and expenses:		
Research and development	$ 24,610	$ 24,087
Selling, general and administrative	11,103	10,959
Total costs and expenses	35,713	35,046
Loss from continuing operations	(35,713)	(35,046)
Interest expense	(7,933)	(4,941)
Interest and other income	3,963	493
Net loss from continuing operations	(39,683)	(39,494)
Net income from discontinued operations, net of tax	5,982	6,483
Net loss	$ (33,701)	$ (33,011)
Basic and diluted net income (loss) per share		
Net loss from continuing operations	$ (0.63)	$ (0.63)
Net income from discontinued operations	0.09	0.10
Net loss	$ (0.54)	$ (0.53)
Weighted-average shares used to compute basic and diluted net income (loss) per share	62,828,765	62,724,775

OMEROS CORPORATION

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEET

(In thousands)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 3,829	$ 11,009
Short-term investments	367,527	183,909
OMIDRIA contract royalty asset, short-term	28,940	28,797
Receivables	10,033	213,221
Prepaid expense and other assets	6,708	6,300
Total current assets	417,037	443,236
OMIDRIA contract royalty asset	119,681	123,425
Right of use assets	21,025	21,762
Property and equipment, net	1,335	1,492
Restricted investments	1,054	1,054
Total assets	$ 560,132	$ 590,969
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 6,446	$ 5,989
Accrued expenses	30,821	30,551
Current portion of unsecured convertible senior notes, net	94,554	94,381
Current portion of OMIDRIA royalty obligation	2,943	1,152
Current portion of lease liabilities	4,427	4,310
Total current liabilities	139,191	136,383
Unsecured convertible senior notes, net	221,209	220,906
OMIDRIA royalty obligation	123,057	125,126
Lease liabilities, non-current	21,287	22,426
Other accrued liabilities, non-current	452	444
Shareholders' equity:		
Common stock and additional paid-in capital	724,354	721,401
Accumulated deficit	(669,418)	(635,717)
Total shareholders' equity	54,936	85,684
Total liabilities and shareholders' equity	$ 560,132	$ 590,969