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): August 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 and six months ended June 30, 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 August 9, 2023, pertaining to Omeros Corporation's financial results for the three and six months ended June 30, 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: August 9, 2023

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

Exhibit 99.1

Omeros Corporation Reports Second Quarter 2023 Financial Results

- Conference Call Today at 8:30 a.m. ET -

SEATTLE, WA – August 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 second quarter ended June 30, 2023, which include:

- Net loss was $37.3 million in the quarter ended June 30, 2023, or $0.59 per share, compared to a net loss in the prior year quarter of $30.8 million, or $0.49 per share. For the six months ended June 30, 2023 our net loss was $71.0 million, or $1.13 per share compared to $63.9 million, or $1.02 per share in the prior year period. Cash burn for the second quarter was $30.1 million.

- For the second quarter of 2023, we earned OMIDRIA royalties of $10.7 million on Rayner Surgical Inc.'s ("Rayner") U.S. net sales of $35.7 million. This compares to earned royalties of $17.2 million during the second quarter of the prior year on U.S. net sales of $34.5 million. The base royalty rate applicable to U.S. net sales of OMIDRIA decreased from 50 percent to 30 percent in December 2022 upon recognition of the $200.0 million milestone payment. The royalty rate applicable to any sales of OMIDRIA outside the U.S. remains unchanged at 15 percent.

- At June 30, 2023, we had $341.3 million of cash, cash equivalents and short-term investments available for operations and debt servicing along with $11.2 million of accounts receivable.

- In May 2023 we had a Type B meeting with the review division at FDA to discuss the planned resubmission of our Biologics License Application ("BLA") for narsoplimab in hematopoietic stem cell transplant-associated thrombotic microangiopathy ("TA-TMA"). Based on the agency's feedback we expect to submit to FDA early next month a detailed plan for analysis of survival data from already-identified external sources.

- In June 2023, results from a pre-specified interim analysis of our ongoing clinical trial of OMS906 in treatment-naïve adults with paroxysmal nocturnal hemoglobinuria ("PNH") were presented at the 2023 congress of the European Hematology Association. Statistically significant and clinically meaningful improvements were observed in all measured markers of hemolysis, including hemoglobin and lactate dehydrogenase. The OMS906 data were identified as one of the top five late-breaking submissions of the congress and were selected for presentation at a special oral session. At the end of July, we performed another analysis of the data in hand through the date of assessment. We continue to be highly encouraged by the results and plan to present the data from this most recent analysis at the upcoming congress of the American Society of Hematology in December.

- The Phase 2 "switch-over" trial evaluating OMS906 in patients demonstrating an unsatisfactory response to treatment with the C5 inhibitor ravulizumab is also underway. Seven of the targeted 12 patients have been enrolled with additional patients currently in screening.

"Our team continued building significant shareholder value throughout the second quarter of 2023," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "Working with FDA, we continue to make progress toward a resubmission of our narsoplimab BLA for TA-TMA and are targeting a mid-2024 FDA decision regarding approval. As we prepare for a good outcome and subsequent market launch establishing narsoplimab as the first drug

approved for life-threatening TA-TMA, we remain on track to read out Phase 3 data later this quarter from our ARTEMIS-IGAN trial aimed at bringing narsoplimab to the large market opportunity of high-proteinuria IgA nephropathy. Our next-generation MASP-2 inhibitor, OMS1029, is in the clinic, looking well-set to be a once-quarterly subcutaneously or intravenously administered therapeutic, and is slated to begin a Phase 2 program next summer – and behind it, progressing toward the clinic, is our orally available small-molecule MASP-2 inhibitor. In the other half of our complement franchise, our Phase 2 clinical asset, OMS906, continues to deliver data consistent with a premier drug targeting the premier enzyme in the alternative pathway, increasing confidence in our objective to make OMS906 the first-line, standard-of-care for a wide range of alternative pathway disorders. At NIDA's request and with its significant grant funding, we are advancing OMS527, our oral PDE7 inhibitor, to a Phase 2 clinical study as a treatment for cocaine use disorder and are considering assessing the drug in a Phase 2 trial for Parkinson's-related levodopa-induced dyskinesia, a crippling unmet need affecting millions of patients. Our cellular and molecular immuno-oncology platforms also continue to mature, and we are working hard to add them to our pipeline of clinical assets. With a cash runway forecasted to fund operations well into 2025, we are strongly positioned to drive our development programs and monetize our assets. Our team's mission is to bring transformational therapeutics to patients who need them – and that requires relentless execution against our development milestones and objectives. I'm proud of the way the Omeros team has executed in the first half of 2023, and I expect that we will continue that positive momentum into the back half of the year."

Second 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 IgA nephropathy, include:

    - In May, we had a Type B meeting with FDA's Division of Nonmalignant Hematology to discuss our planned resubmission of the BLA for narsoplimab in TA-TMA. At the meeting we received guidance from the Agency on our proposal to collect and analyze certain external survival data and to include these analyses in the BLA resubmission. Based on the Agency's guidance, we expect to submit to FDA a detailed plan for analysis of those survival data, which are from already-identified external sources. The proposal will be submitted as a Type B meeting request, with FDA's response expected within 60 days. After receiving FDA's feedback on our detailed plan, we intend to conduct the analyses and, together with additional new supportive data, plan to resubmit the BLA. Assuming the full duration of relevant FDA review periods, we are targeting an approval decision by FDA in mid-2024. We expect next to provide investors with an update following BLA resubmission.

    - 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 later this quarter.

    - In late May, a review article authored by an international group of experts was published in *Kidney International*. The article describes kidney biopsies of IgA nephropathy patients, which consistently showed glomerular deposition of mannan-binding lectin together with IgA1 in up to 50% of patients with IgA nephropathy. Glomerular deposition of pattern-recognition molecules in the lectin pathway is associated with more severe glomerular damage and more severe proteinuria and hematuria. Research also suggests that lectin pathway activation contributes to tubulointerstitial fibrosis in IgA nephropathy and other proteinuric kidney disease.

- Our research efforts in COVID-19 and acute respiratory distress syndrome ("ARDS") continues at the Omeros-Cambridge Center for Complement and Inflammation Research ("OC3IR"). A manuscript detailing the beneficial effects of MASP-2 inhibition on both symptoms and survival in chemically induced ARDS was published at the end of May in *Frontiers in Immunology*. Another manuscript has been submitted for publication describing the pulmonary and central nervous systems benefits of MASP-2 blockade on symptoms and survival in well-established animal models of COVID-19 ARDS. Discussions are ongoing with the U.S. Government regarding development of narsoplimab for use in severe COVID-19 and other forms of ARDS.

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

- Dosing in a Phase 1 multiple-ascending-dose study of OMS1029 in healthy subjects was initiated on schedule in July. In a single-ascending dose Phase 1 clinical trial completed in early 2023, OMS1029 was well tolerated and no safety concerns were identified. Preliminary pharmacokinetic and pharmacodynamic ("PK/PD") data from that study showed dose-proportional exposure and sustained lectin pathway inhibition, consistent with once-quarterly intravenous or subcutaneous dosing. A Phase 2 program is slated to begin next summer.

- Recent developments regarding OMS906, our lead monoclonal antibody targeting mannan-binding lectin-associated serine protease-3 ("MASP-3"), the key activator of the alternative pathway, include:

  - Enrollment is ongoing in our Phase 2 clinical trial evaluating OMS906 in PNH patients who have had an unsatisfactory response to the C5 inhibitor ravulizumab. The 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. Enrollment is targeted for 12 patients, 7 of whom have already been enrolled with others in screening.

  - Enrollment has been completed in the clinical trial treating patients who are not receiving complement inhibitors at entry (i.e., treatment-naïve). Data collection continues and an abstract detailing the most recent data analysis from late July has been submitted to the American Society of Hematology Annual Meeting to be held in December 2023.

  - Our clinical program evaluating OMS906 in patients with complement 3 glomerulopathy ("C3G") is also underway. We are amending the dose in this trial based on data from our ongoing and completed clinical trials of OMS906 and expect soon to begin enrolling C3G patients.

  - We recently engaged a group of expert hematologists for an advisory panel that yielded key insights on the current standard of care for the treatment of PNH, the unmet patient need and other factors affecting the market for PNH therapeutics. The session informed our clinical development plans and commercial strategy for OMS906 and, more generally, for our alternative pathway inhibitor program.

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

  - We continue to pursue development of our lead orally administered PDE7 inhibitor compound for the treatment of cocaine use disorder ("CUD"). This work was initiated at the request of, and is being performed in collaboration with, the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health. The development efforts are supported by grant funding from NIDA. The three-year, $6.69 million grant 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. Previously, a Phase 1 clinical trial of the study drug in healthy subjects was successfully completed.

  - Along with collaborators at Emory University we continue to evaluate the potential of our PDE7 inhibitors to treat levodopa-induced dyskinesias ("LID"). LID is caused by prolonged treatment with levodopa, the most prescribed treatment for the over 10 million patients with Parkinson's disease worldwide. LID is reported to affect 50 percent or more of levodopa-treated patients with Parkinson's disease. We are evaluating the data and will file patent applications as appropriate.

Financial Results

Net loss for the quarter ended June 30, 2023 was $37.3 million, or $0.59 per share. This compares to a net loss in the prior year quarter of $30.8 million, or $0.49 per share. Cash burn for the quarter ended June 30, 2023 was $30.1 million, an amount artificially inflated by $3.4 million corresponding to Rayner's late payment of royalties received in July but due in June 2023.

For the second quarter of 2023, we earned OMIDRIA royalties of $10.7 million on Rayner's U.S. net sales of $35.7 million. This compares to earned royalties of $17.2 million during the second quarter of the prior year on U.S. net sales of $34.5 million. The recognition of the $200 million milestone payment from Rayner in December 2022 triggered a reduction of our U.S. base royalty rate from 50 percent to 30 percent. Royalties are recorded as a reduction of the OMIDRIA contract royalty asset on our balance sheet.

Total costs and expenses for the second quarter of 2023 were $40.9 million compared to $37.4 million for the second quarter of 2022. The increase was primarily due to the advancement of our OMS906 program and incremental clinical trial costs for narsoplimab. This increase was partially offset by reductions in selling, general and administrative expenses.

Interest expense during the second quarter of 2023 was $7.9 million compared to $4.9 million during the prior year quarter. 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 second quarter of 2023, we earned $4.5 million in interest and other income compared to $0.7 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 $7.0 million, or $0.11 per share, in the second quarter of 2023 compared to $10.8 million, or $0.17 per share, in the second quarter of 2022.

As of June 30, 2023, we had $341.3 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 $11.2 million in accounts receivable.

Conference Call Details

Omeros' management will host a conference call and webcast to discuss the financial results and to provide an update on business activities. The call will be held today at 5:30 a.m. Pacific Time; 8:30 a.m. Eastern Time.

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

To access the live conference call via phone, participants must register at this link to receive a unique PIN. Once registered, you will have two options: (1) Dial in to the conference line provided at the registration site using the PIN provided to you, or (2) choose the "Call Me" option, which will instantly dial the phone number you provide. Should you lose your PIN or registration confirmation email, simply re-register to receive a new PIN.

A replay of the call will be made accessible online at https://investor.omeros.com/archived-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 the anticipated next steps in relation to the biologics license application for narsoplimab, the timing of regulatory events, the availability of clinical trial data, the prospects for obtaining FDA approval of narsoplimab in any indication, expectations regarding the initiation or continuation of clinical trials evaluating Omeros’ drug candidates and the anticipated availability of data therefrom, and expectations regarding the sufficiency of the Company’s capital resources to fund operations, 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, the Company’s 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.

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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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Costs and expenses:				
Research and development	$ 29,639	$ 23,516	$ 54,249	$ 47,603
Selling, general and administrative	11,260	13,922	22,363	24,881
Total costs and expenses	40,899	37,438	76,612	72,484
Loss from operations	(40,899)	(37,438)	(76,612)	(72,484)
Interest expense	(7,932)	(4,927)	(15,865)	(9,868)
Interest and other income	4,537	670	8,500	1,163
Net loss from continuing operations	(44,294)	(41,695)	(83,977)	(81,189)
Net income from discontinued operations	7,000	10,846	12,982	17,329
Net loss	$ (37,294)	$ (30,849)	$ (70,995)	$ (63,860)
Basic and diluted net income (loss) per share:				
Net loss from continuing operations	$ (0.70)	$ (0.66)	$ (1.34)	$ (1.30)
Net income from discontinued operations	0.11	0.17	0.21	0.28
Net loss	$ (0.59)	$ (0.49)	$ (1.13)	$ (1.02)
Weighted-average shares used to compute basic and diluted net income (loss) per share	62,837,125	62,730,015	62,832,991	62,727,395

OMEROS CORPORATION

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEET

(In thousands)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 6,603	$ 11,009
Short-term investments	334,680	183,909
OMIDRIA contract royalty asset, short-term	29,084	28,797
Receivables	11,190	213,221
Prepaid expense and other assets	7,001	6,300
Total current assets	388,558	443,236
OMIDRIA contract royalty asset	115,802	123,425
Right of use assets	20,258	21,762
Property and equipment, net	1,749	1,492
Restricted investments	1,054	1,054
Total assets	$ 527,421	$ 590,969
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 9,552	$ 5,989
Accrued expenses	29,793	30,551
Current portion of unsecured convertible senior notes, net	94,730	94,381
Current portion of OMIDRIA royalty obligation	4,777	1,152
Current portion of lease liabilities	4,686	4,310
Total current liabilities	143,538	136,383
Unsecured convertible senior notes, net	221,516	220,906
OMIDRIA royalty obligation	120,939	125,126
Lease liabilities, non-current	20,422	22,426
Other accrued liabilities, non-current	496	444
Shareholders' equity:		
Common stock and additional paid-in capital	727,222	721,401
Accumulated deficit	(706,712)	(635,717)
Total shareholders' equity	20,510	85,684
Total liabilities and shareholders' equity	$ 527,421	$ 590,969