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, 2022

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 August 9, 2022, Omeros Corporation issued a press release announcing financial results for the three and six months ended June 30, 2022. 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, 2022, pertaining to Omeros Corporation's financial results for the three and six months ended June 30, 2022.
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, 2022

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

Omeros Corporation Reports Second Quarter 2022 Financial Results

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

SEATTLE, WA – August 9, 2022 – Omeros Corporation (Nasdaq: OMER), 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 inflammation and immunologic diseases, including complement-mediated diseases and cancers, today announced recent highlights and developments as well as financial results for the second quarter ended June 30, 2022, which include:

- For the quarter ended June 30, 2022, Omeros earned royalties of $17.2 million on net sales of the company's former ophthalmology product OMIDRIA®. Royalties earned in the quarter represent 50 percent of net sales of OMIDRIA by Rayner Surgical, Inc. (Rayner), which purchased Omeros' ophthalmology assets in December 2021. Rayner's reported net sales of $34.5 million for the second quarter of 2022, all of which were in the U.S., establish a new all-time high for quarterly OMIDRIA sales and represent a $5.7 million increase over net sales of $28.8 million reported by Omeros for the second quarter of last year.

- Net loss in 2Q 2022 was $30.9 million, or $0.49 per share, which included $3.7 million of non-cash expenses, or $0.06 per share. This compares to a net loss of $28.6 million, or $0.46 per share for the prior year quarter, which included $3.9 million of non-cash expenses, or $0.06 per share.

- At June 30, 2022, Omeros had $122.6 million of cash, cash equivalents and short-term investments available for operations, which is a reduction of $19.7 million from March 31, 2022. In addition, Omeros had $14.5 million in net receivables available for operations at June 30, 2022.

- In June 2022, Omeros submitted to the United States Food and Drug Administration (FDA) a request for Formal Dispute Resolution regarding the Complete Response Letter (CRL) issued by FDA last year regarding the Company's biologics license application (BLA) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA). Formal dispute resolution is an official pathway that enables a sponsor to appeal a decision by an FDA division to a higher authority within FDA, in this case the Office of New Drugs (OND). Last month, in accordance with the standard dispute resolution procedure, Omeros had a formal meeting with the OND official assigned to decide the dispute. A decision is expected in August 2022.

"We remain confident that approval of narsoplimab in TA-TMA is warranted, and we look forward to OND's decision later this month," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "In addition to FDA's decision on narsoplimab approval, a series of value-driving milestones have aligned over the next few quarters: data from our Phase 3 trial of narsoplimab in IgA nephropathy are on track for readout by mid-next year; our MASP-3 inhibitor OMS906 is starting trials in PNH and C3 glomerulopathy with efficacy data targeted by early next year; about that same time, we expect data from our Phase 1 trial of OMS1029, our long-acting MASP-2 inhibitor, which began dosing earlier this week; also in early 2023, our PDE7 inhibitor OMS527 should have data available in a clinically predictive primate model of levodopa-induced dyskinesias; and, with separate payment for OMIDRIA reconfirmed by CMS in its recently released proposed rule for the Outpatient Prospective Payment System, we expect continuing growth in our royalty stream and, should OMIDRIA obtain long-term reimbursement, to secure the $200-million milestone payment."

Second Quarter and Recent Clinical Developments

- Recent developments regarding narsoplimab, Omeros' lead monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2) in advanced clinical programs for the treatment of TA-TMA, immunoglobulin A (IgA) nephropathy, atypical hemolytic uremic syndrome (aHUS) and severely ill COVID-19 patients, include the following:

    - Enrollment in Omeros' Phase 3 ARTEMIS-IGAN trial continues to progress toward an anticipated readout of 9-month data on proteinuria by mid-next year.

    - The Omeros teams in Cambridge, UK and Seattle recently published two manuscripts detailing the company's latest COVID-19-related discoveries, the first by Ali et al. in *Frontiers in Immunology* and the second by Lynch et al. in *Clinical and Translational Medicine*. Together, these publications describe the findings that:

        - Patients with severe COVID-19 early in disease show marked complement consumption driven by lectin pathway hyperactivation, causing secondary hypocomplementemia and loss of complement-mediated immune protection against microbial infection. This hypocomplementemia increases the risk of clinically severe infections, a common cause of morbidity and death in COVID-19.

        - Narsoplimab restores complement function and bactericidal activity, preventing risk of secondary infection.

    - Narsoplimab is also being evaluated for the treatment of hospitalized COVID-19 patients in the I-SPY COVID-19 platform trial sponsored by Quantum Leap Healthcare Collaborative (QLHC). Omeros looks forward to QLHC's disclosure of the narsoplimab results.

  Recent developments regarding OMS906, Omeros' lead monoclonal antibody targeting MASP-3, the key activator of the alternative pathway, and OMS1029, the company's long-acting, next-generation MASP-2 inhibitor, include the following:

    - In July, OMS906 received designation from FDA as an orphan drug for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). Orphan-drug designation is granted by FDA to encourage development of a drug that targets a condition affecting fewer than 200,000 U.S. patients annually. The benefits of orphan drug designation include seven years of market exclusivity following marketing approval, tax credits on U.S. clinical trials, eligibility for orphan drug grants, and waiver of certain administrative fees.

    - To accelerate obtaining OMS906 efficacy data, in addition to the Phase 1b trial expected to begin enrolling soon and evaluating OMS906 in patients with PNH who have had an unsatisfactory response to the C5 inhibitor ravulizumab, Omeros is expanding its program of OMS906 clinical trials to include treatment-naïve PNH patients and complement 3 (C3) glomerulopathy patients as well as one or more related indications. Efficacy data in these indications are targeted by early 2023.

    - Omeros has submitted an abstract describing the results of the OMS906 Phase 1 study for presentation at a major medical congress later this year. Preliminary results from the Phase 1 study were previously reported and no safety signals of concern were noted.

    - A Phase 1 clinical trial assessing safety, tolerability and pharmacokinetics/pharmacodynamics (PK/PD) of OMS1029 in healthy subjects is underway, with the first dose administered earlier this week. Designed for convenient dosing, OMS1029 is expected to enable Omeros to pursue a range of indications complementary to those for narsoplimab. Based on animal PK/PD data to date, dosing in humans is expected to be once-monthly to once-quarterly by subcutaneous or intravenous administration.

Financial Results

On December 23, 2021, Rayner acquired OMIDRIA and certain related assets and liabilities. The completion of the sale required Omeros to reclassify all revenues and expenses related to OMIDRIA as discontinued operations for fiscal year 2021 in its financial statements.

During the second quarter of 2022, Omeros earned royalties of $17.2 million on sales of OMIDRIA, which were recorded as a reduction from the OMIDRIA contract royalty asset. The company also recorded $10.1 million of income in discontinued operations, primarily representing interest income and remeasurement adjustments to the OMIDRIA contract royalty asset.

Total costs and expenses for the second quarter of 2022 were $37.4 million compared to $45.6 million for the second quarter of 2021. The decrease was primarily due to the timing of narsoplimab manufacturing activities and a reduction in U.S. TA-TMA pre-launch activities.

Net loss was $30.9 million in the second quarter of 2022, or $0.49 per share, which included $3.7 million of non-cash expenses, or $0.06 per share. This compares to a net loss of $28.6 million, or $0.46 per share, including $3.9 million of non-cash expenses, or $0.06 per share, in 2Q 2021.

As of June 30, 2022, the company had $122.2 million of cash, cash equivalents and short-term investments with an additional $14.5 million in receivables, net.

Conference Call Details

To access the live conference call via phone, please dial (833) 634-2592 from the United States and Canada or (412) 902-4100 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 (877) 344-7529 from the United States, (412) 317-0088 internationally, and (855) 669-9658 from Canada. The replay access code is 4990130.

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. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is advancing in clinical programs for paroxysmal nocturnal hemoglobinuria (PNH), complement 3 (C3) glomerulopathy and one or more related indications. 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 expectations with regard to Omeros' pursuit of regulatory approval for narsoplimab in TA-TMA, including expectations regarding the potential or anticipated outcomes of its formal dispute resolution request, and 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, 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 impact of COVID-19 on our business, 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 1, 2022. 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 CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Costs and expenses:				
Research and development	$ 23,516	$ 30,126	$ 47,603	$ 62,630
Selling, general and administrative	13,922	15,484	24,881	28,270
Total costs and expenses	37,438	45,610	72,484	90,900
Loss from continuing operations	(37,438)	(45,610)	(72,484)	(90,900)
Interest expense	(4,927)	(4,910)	(9,868)	(9,807)
Other income	670	333	1,163	751
Net loss from continuing operations	(41,695)	(50,187)	(81,189)	(99,956)
Net income from discontinued operations	10,846	21,594	17,329	36,273
Net loss	$ (30,849)	$ (28,593)	$ (63,860)	$ (63,683)
Basic and diluted net income (loss) per share				
Net loss from continuing operations	(0.66)	(0.80)	$ (1.30)	$ (1.61)
Net income from discontinued operations	0.17	0.34	0.28	0.59
Net loss	$ (0.49)	$ (0.46)	$ (1.02)	$ (1.02)
Weighted-average shares used to compute basic and diluted net income (loss) per share	62,730,015	62,373,521	62,727,395	62,154,714

(1) The sale of OMIDRIA has been accounted for as the sale of an asset. Accordingly, we have reclassified all revenues and expenses related to OMIDRIA to net income from discontinued operations for the three and six months ended June 30, 2021 in our financial statements.

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 122,562	$ 157,266
OMIDRIA contract royalty asset	170,606	184,570
Total assets	345,638	419,268
Total current liabilities	38,501	51,789
Lease liabilities	28,665	34,381
Unsecured convertible senior notes, net	314,358	313,458
Total shareholders' equity (deficit)	(32,702)	23,780
Working capital	154,221	196,167

OMEROS CORPORATION
UNAUDITED CONSOLIDATED SUPPLEMENTAL DATA
(In thousands)

The following schedule presents a rollforward of the OMIDRIA contract royalty asset:

OMIDRIA contract royalty asset at December 31, 2021	$ 184,570
Royalties earned	(31,062)
Royalty interest income and remeasurement adjustments	17,098
OMIDRIA contract royalty asset at June 30, 2022	$ 170,606

Net income from discontinued operations is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(In thousands)			
Product sales, net	$ —	$ 28,823	$ —	$ 49,884
Royalty interest income and remeasurement adjustments	10,102	—	17,098	—
Total	10,102	28,823	17,098	49,884
Other income, costs and expenses, net	(744)	7,229	(231)	13,611
Net income from discontinued operations	$ 10,846	$ 21,594	$ 17,329	$ 36,273