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 10, 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 May 10, 2022, Omeros Corporation issued a press release announcing financial results for the three months ended March 31, 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 May 10, 2022, pertaining to Omeros Corporation's financial results for the three months ended March 31, 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: May 10, 2022

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 First Quarter 2022 Financial Results

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

SEATTLE, WA – May 10, 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 first quarter ended March 31, 2022, which include:

- On December 23, 2021, Omeros completed the sale of its commercial ophthalmic product OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% and certain related assets and liabilities to Rayner Surgical Inc. ("Rayner"). As a result of the transaction, the company reclassified all revenues and expenses related to OMIDRIA to discontinued operations for fiscal year 2021 in its financial statements. Omeros is entitled to royalties on Rayner's worldwide net sales of OMIDRIA at rates that vary based on geography and certain regulatory contingencies. The royalty rate for U.S. net sales of OMIDRIA is currently 50 percent.

- For the quarter ended March 31, 2022, Omeros earned royalties of $13.8 million based on Rayner's net sales of $27.7 million, all of which were in the U.S. This is a $6.6 million increase from the $21.1 million of OMIDRIA net sales reported by Omeros in the prior year quarter.

- Net loss was $33.0 million in the current quarter, or $0.53 per share, which included $4.2 million of non-cash expenses, or $0.07 per share. This compares to a net loss of $35.1 million, or $0.57 per share for the prior year quarter, which included $4.1 million of non-cash expenses, or $0.07 per share.

- At March 31, 2022, Omeros had $142.2 million of cash, cash equivalents and short-term investments available for operations, which is a reduction of $15.0 million from December 31, 2021. In addition, at March 31, 2022 Omeros had $16.3 million in receivables, consisting primarily of OMIDRIA royalties related to the first quarter, which are due for payment this month.

- In February 2022, Omeros had a Type A post-action meeting with the United States Food and Drug Administration (FDA) to discuss 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). FDA was delayed in providing official minutes of the meeting, in which the review division repeated a number of critiques that the Company felt had been adequately addressed or were inaccurate. After close consultation with outside legal and regulatory advisors, Omeros has prepared and expects soon to submit a request for formal dispute resolution. 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. Omeros' request is for regular approval based on the data in the existing BLA.

"Following our Type A post-action meeting with FDA and preparing our draft request for formal dispute resolution, we remain highly confident in the strength of our data and of the entirety of our BLA," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "We believe that the BLA warranted approval last year and, given the immediate patient need for narsoplimab, that formal dispute resolution represents the most expeditious path to approval. We now are finalizing the request with our team of regulatory and legal advisors and expect to submit it within a couple of weeks. Physician support is broad, our case for appeal is strong, and we expect to be successful. In addition to our

focus on regulatory approval, we believe that there are a series of value-creating events throughout the remainder of 2022, including OMS906 data in patients with paroxysmal nocturnal hemoglobinuria, data from our efforts in COVID-19, as well as updates on our Phase 1 study evaluating our long-acting MASP-2 inhibitor OMS1029, completion of enrollment for the proteinuria endpoint in our narsoplimab ARTEMIS-IgAN trial, and the potential to earn an OMIDRIA-related $200-million commercial milestone payment."

First Quarter and Recent 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:

    - In April 2022, a manuscript detailing the results of Omeros' pivotal study assessing efficacy and safety of narsoplimab for the treatment of TA-TMA was published in the *Journal of Clinical Oncology* (JCO), the flagship publication of the American Society of Clinical Oncology. The manuscript, entitled "Narsoplimab, a Mannan-Binding Lectin-Associated Serine Protease-2 Inhibitor, for the Treatment of Adult Hematopoietic Stem-Cell Transplantation–Associated Thrombotic Microangiopathy" is available online and will be included in an upcoming print volume of JCO.

    - Omeros engaged with key stakeholders in the transplant community through its presence at TANDEM 2022, the joint annual meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR), which was held last month in Salt Lake City. As part of the conference, Omeros received an award from the President of ASTCT in recognition of Omeros' work in raising awareness of TA-TMA and advancing the medical and scientific understanding in the field.

    - 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. To date, no drug investigated in the trial has been reported to show a benefit relative to the background therapy in the trial. Quantum's analysis of the narsoplimab data is being finalized, and we all look forward to sharing the outcome of the trial.

    - Enrollment in Omeros' Phase 3 Artemis IgAN trial continues to progress towards an anticipated read out of 9-month follow-up data on proteinuria in the first half of next year. Our investigational new drug application for narsoplimab in IgAN has now been approved by the Chinese regulatory authority. We look forward to completing the remaining regulatory requirements and initiating enrollment there as soon as possible.

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

    - Omeros continues its preparations to initiate a Phase 1b trial of OMS906 in patients with paroxysmal nocturnal hemoglobinuria (PNH). Enrollment is expected to begin this summer. As previously disclosed, dosing in the single-ascending-dose study of OMS906 in healthy subjects is completed. There were no safety signals of concern, and pharmacokinetic/pharmacodynamic (PK/PD) data support once-monthly to once-quarterly subcutaneous or intravenous dosing.

    - Preparations are also underway for a Phase 1 trial assessing safety and tolerability and PK/PD of OMS1029 in healthy human subjects. First-in-human-enabling toxicology studies are complete and there was no safety signal of concern. Dosing in humans is expected to be once-monthly to once-quarterly by subcutaneous or intravenous administration based on animal PK/PD data to date. Enrollment is targeted to begin this summer.

Financial Results

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

Upon closing of the sale of OMIDRIA, Omeros recorded an OMIDRIA contract royalty asset of $184.6 million representing the minimum expected net present value of future U.S. royalty payments. During the first quarter of 2022, we earned royalties of $13.8 million on sales of OMIDRIA which we recorded as a reduction to the OMIDRIA contract royalty asset. We also recorded $7.0 million of income in discontinued operations representing interest income and remeasurement adjustments to the OMIDRIA contract royalty asset.

Total costs and expenses for the first quarter of 2022 were $35.0 million compared to $45.3 million for the first quarter of 2021. The decrease was primarily due to reduced narsoplimab manufacturing activities and reduced narsoplimab pre-launch marketing activities.

Net loss was $33.0 million in the first quarter of 2022, or $0.53 per share, which included $4.2 million of non-cash expenses, or $0.07 per share. This compares to a net loss of $35.1 million, or $0.57 per share, which included non-cash expenses of $4.1 million, or $0.07 per share.

As of March 31, 2022, the company had $142.2 million of cash, cash equivalents and short-term investments, a reduction of $15.0 million from December 31, 2021, and $16.3 million in receivables, net.

Conference Call Details

To access the live conference call via phone, please dial (844)831-4029 from the United States and Canada or (920) 663-6278 internationally. The participant passcode is 1198541. A telephone replay will be available for one week following the call and may be accessed by dialing (855) 859-2056 from the United States and Canada or (404) 537-3406 internationally. The replay passcode is 1198541.

To access the live or subsequently archived webcast of the conference call on the internet, go to the company's 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 diseases, including complement-mediated diseases and cancers related to dysfunction of the immune system, as well as 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 (HSCT-TMA). Narsoplimab is also in multiple late-stage clinical development programs focused on other complement-mediated disorders, including IgA nephropathy, atypical hemolytic uremic syndrome and COVID-19. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is initiating a Phase 1b clinical program in paroxysmal nocturnal hemoglobinuria (PNH). 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 Omeros' pursuit of regulatory approval for narsoplimab in HSCT-TMA, including expectations regarding submission of a formal dispute resolution request and the potential or anticipated outcomes thereof, and expectations regarding the initiation or continuation of clinical trials evaluating Omeros' drug candidates and the anticipated availability of data therefrom, 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:

Jennifer Cook Williams
Cook Williams Communications, Inc.
Investor and Media Relations
IR@omeros.com

OMEROS CORPORATION
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	2021(1)
Costs and expenses:		
Research and development	$ 24,087	$ 32,504
Selling, general and administrative	10,959	12,786
Total costs and expenses	35,046	45,290
Loss from continuing operations	(35,046)	(45,290)
Interest expense	(4,941)	(4,897)
Other income	493	418
Net loss from continuing operations	(39,494)	(49,769)
Net income from discontinued operations	6,483	14,679
Net loss	$ (33,011)	$ (35,090)
Basic and diluted net income (loss) per share:		
Net loss from continuing operations	$ (0.63)	$ (0.81)
Net income from discontinued operations	0.10	0.24
Net loss	$ (0.53)	$ (0.57)
Weighted-average shares used to compute basic and diluted net income (loss) per share	62,724,775	61,928,511

(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 the quarter ending March 31, 2021 in our financial statements.

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 142,234	$ 157,266
OMIDRIA contract royalty asset	177,735	184,570
Total assets	369,263	419,268
Total current liabilities	35,066	51,789
Lease liabilities	28,221	34,381
Unsecured convertible senior notes, net	313,904	313,458
Total shareholders' equity (deficit)	(4,925)	23,780
Working capital	175,156	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	(13,831)
Royalty interest income and remeasurement adjustments	6,996
OMIDRIA contract royalty asset at March 31, 2022	$ 177,735

Net income from discontinued operations is as follows:

	Three Months Ended March 31,	
	2022	2021
Product sales, net	$ —	$ 21,061
Royalty interest income and remeasurement adjustments	6,996	—
Total	6,996	21,061
Costs and expenses	513	6,382
Net income from discontinued operations	$ 6,483	$ 14,679