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, 2021

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, 2021, Omeros Corporation issued a press release announcing financial results for the three months ended March 31, 2021. 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, 2021, pertaining to Omeros Corporation's financial results for the three months ended March 31, 2021.
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, 2021

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 2021 Financial Results

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

SEATTLE, WA – May 10, 2021 – Omeros Corporation (Nasdaq: OMER), a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, immunologic diseases (e.g., complement-mediated diseases and cancers) and central nervous system disorders, today announced recent highlights and developments as well as financial results for the first quarter ended March 31, 2021, which include:

- OMIDRIA revenues for the first quarter of 2021 were $21.1 million compared to $10.6 million in the fourth quarter of 2020. The increase over the prior quarter reflects limited fourth-quarter sales due to delayed confirmation (issued in December) by the Centers for Medicare and Medicaid Services (CMS) that OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% receives separate payment when used in the ambulatory surgery center (ASC) setting.

- Net loss in the first quarter of 2021 was $35.1 million, or $0.57 per share, including non-cash expenses of $4.1 million, or $0.07 per share. This compares to a net loss of $37.3 million, or $0.60 per share, which included non-cash expenses of $3.5 million, or $0.07 per share, for the previous quarter.

- At March 31, 2021, Omeros had cash, cash equivalents and short-term investments available for operations of $100.5 million.

- Dosing of patients with narsoplimab in the I-SPY COVID-19 platform trial began in March 2021. The platform trial, sponsored by Quantum Leap Healthcare Collaborative and partly funded by BARDA, is enrolling patients nationwide to evaluate potential therapies for the treatment of critically ill COVID-19 patients.

- Omeros' Biologics License Application (BLA) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangipathy (HSCT-TMA or TA-TMA) is under priority review by the U.S. FDA with an action date of July 17, 2021 under the Prescription Drug User Fee Act (PDUFA).

- In late April, the Centers for Disease Control and Prevention (CDC) and CMS approved a new ICD-10 diagnosis code for TA-TMA, creating a disease-specific code by which facilities will bill for services, and two new ICD-10 procedural codes that allow physicians to bill for the administration of narsoplimab.

"2021 is off to a strong start as we make great progress toward the anticipated launch of narsoplimab for TA-TMA while building momentum with our ophthalmic drug OMIDRIA following CMS' confirmation of separate payment for OMIDRIA in the ASC setting," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "Narsoplimab dosing is well underway in the I-SPY COVID-19 platform trial, and the need for a therapeutic to treat critically ill COVID-19 patients is receiving increased focus from both U.S. and international agencies. Looking further across our franchise of complement inhibitors, two other narsoplimab Phase 3 programs are running in IgA nephropathy and aHUS, we expect initial data readout next month from the Phase 1 trial of our MASP-3 inhibitor OMS906, and our subcutaneously delivered long-acting MASP-2 inhibitor OMS1029 is slated to enter the clinic in the first half of next year. Our preclinical programs are also progressing, led by our efforts to deliver a GPR174 inhibitor to the clinic as quickly as possible. With the PDUFA date for narsoplimab in TA-TMA rapidly approaching, we remain committed to bringing a long line of important, first-in-class drugs to market."

First Quarter and Recent Developments

- Recent developments regarding OMIDRIA include the following:
    - Omeros continued to add new ASC customers in the first quarter of 2021, including seven large ASC chains and private equity groups. The total number of purchasing ASCs increased by 43% in the first quarter over the previous quarter.
    - A manuscript on pain control and reduction of opioid use intraoperatively with the use of OMIDRIA during cataract surgery has been submitted for publication. Another manuscript on the perioperative use of opioids in cataract surgery pain management and the role of non-opioid alternatives like OMIDRIA has also been submitted for publication.
    - The Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act has been re-introduced in the Senate. The NOPAIN Act would extend separate payment for non-opioid alternatives like OMIDRIA in both ASCs and hospital outpatient departments on a renewable five-year basis. Currently, OMIDRIA is separately paid in the ASC setting.
- Recent developments regarding narsoplimab, Omeros' lead human 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 critically ill COVID-19 patients, include the following:
    - Data from the pivotal trial of narsoplimab in TA-TMA was featured in a podium presentation at the annual European Society for Blood and Marrow Transplantation (EBMT) meeting in March.
    - An abstract on narsoplimab treatment in adults with high-risk TA-TMA has also been accepted for oral presentation at the 2021 Congress of the European Hematology Association (EHA) in June.
    - Discussions with the U.S. and foreign governments regarding funding and manufacturing support for narsoplimab are ongoing.
- Updates regarding Omeros' other development programs and platforms include the following:
    - Omeros has completed all of the intravenous cohorts and the first subcutaneous dosing cohort in the single ascending dose study in its Phase 1 clinical trial evaluating OMS906, the company's inhibitor of MASP-3, the key activator of the alternative pathway of complement. Initial data from the placebo-controlled, double-blind, single-ascending-dose and multiple-ascending-dose trial are expected later this quarter.
    - A paper detailing the mechanism of action of PDE7 inhibition in nicotine addiction will soon be published in the peer reviewed *Journal of Neuroscience*. Omeros has completed a successful Phase 1 trial with OMS527, its PDE7 inhibitor.

Financial Results

For the first quarter of 2021, OMIDRIA revenues were $21.1 million compared to $10.6 million for the fourth quarter of 2020. The uncertainty around OMIDRIA's reimbursement status affected revenues in the fourth quarter and extending into early February 2021.

Total costs and expenses for the first quarter of 2021 were $51.7 million compared to $47.2 million for the first quarter of 2020. The increase was primarily due to research and development expenses related to narsoplimab manufacturing. Until approval for narsoplimab in TA-TMA is certain, manufacturing costs for narsoplimab are expensed as incurred instead of included as inventory.

For the three months ended March 31, 2021, Omeros reported 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. This compares to a net loss in the previous quarter of $37.3 million, or $0.60 per share, which included non-cash expenses of $3.5 million, or $0.07 per share.

As of March 31, 2021, the company had $100.5 million of cash, cash equivalents and short-term investments. The company also has a line of credit, which permits borrowing up to the lesser of 85 percent of eligible accounts receivable less certain reserves and $50.0 million.

On March 1, 2021, the company entered into an “at the market” sales agreement which allows the company to sell, from time to time, up to $150.0 million of its common stock.

Conference Call Details

Omeros’ management will host a conference call to discuss the financial results and to provide an update on business activities. The call will be held today at 1:30 p.m. Pacific Time; 4:30 p.m. Eastern Time. 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 6999269. 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 6999269.

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 a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting inflammation, immunologic diseases (e.g., complement-mediated diseases and cancers) and central nervous system disorders. Its commercial product OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% continues to gain market share in cataract surgery. Omeros’ lead MASP-2 inhibitor narsoplimab targets the lectin pathway of complement and is the subject of a biologics license application under priority review by FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. 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 in a Phase 1 clinical trial, and the company’s PDE7 inhibitor program OMS527, targeting addiction and movement disorders, has successfully completed a Phase 1 trial. Omeros’ pipeline holds a diverse group of preclinical programs including a proprietary-asset-enabled antibody-generating technology and a proprietary GPCR platform through which it controls 54 GPCR drug targets and their corresponding compounds. One of these novel targets, GPR174, modulates a new cancer immunity axis recently discovered by Omeros, and the company is advancing GPR174-targeting antibodies and small-molecule inhibitors.

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 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, risks associated with product commercialization and commercial operations, 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 commercial 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 (SEC) on March 1, 2021. 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 CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	2020
Revenue:		
Product sales, net	$ 21,061	$ 23,537
Costs and expenses:		
Cost of product sales	263	267
Research and development	33,358	28,911
Selling, general and administrative	18,052	18,036
Total costs and expenses	51,673	47,214
Loss from operations	(30,612)	(23,677)
Interest expense	(4,897)	(5,903)
Other income	419	549
Net loss	$ (35,090)	$ (29,031)
Comprehensive loss	$ (35,090)	$ (29,031)
Basic and diluted net loss per share	$ (0.57)	$ (0.53)
Weighted-average shares used to compute basic and diluted net loss per share	61,928,511	54,299,813

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	March 31, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 100,483	$ 134,953
Working capital	89,048	114,549
Restricted investments	1,054	1,055
Total assets	161,444	181,042
Total current liabilities	43,434	36,736
Lease liabilities	31,609	32,552
Unsecured convertible senior notes, net	312,159	236,288
Accumulated deficit	(912,459)	(872,672)
Total shareholders' deficit	(221,955)	(120,752)