# 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, 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 August 9, 2021, Omeros Corporation issued a press release announcing financial results for the three and six months ended June 30, 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 August 9, 2021, pertaining to Omeros Corporation's financial results for the three and six months ended June 30, 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: August 9, 2021

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 2021 Financial Results**

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

**SEATTLE, WA – August 9, 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 second quarter ended June 30, 2021, which include:

- OMIDRIA revenues for the second quarter of 2021 were $28.8 million compared to $21.1 million in the first quarter. The 37 percent increase over the prior quarter primarily reflects growth in sales of OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% in ambulatory surgery centers (ASCs).

- Net loss in the second quarter of 2021 was $28.6 million, or $0.46 per share, including non-cash expenses of $3.9 million, or $0.06 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, for the previous quarter.

- At June 30, 2021, Omeros had cash, cash equivalents and short-term investments available for operations of $73.7 million.

- 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 October 17, 2021 under the Prescription Drug User Fee Act (PDUFA).

- Omeros announced preliminary results from the Phase 1 clinical trial of OMS906, the company's MASP-3 inhibitor, which showed that (i) OMS906 was well tolerated at all doses tested and (ii) human pharmacokinetic and pharmacodynamic data are consistent with once-monthly or less frequent subcutaneous dosing.

"In the second quarter of 2021, Omeros achieved a number of important milestones," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "As OMIDRIA sales continue to grow, CMS in its recent OPPS Proposed Rule reaffirmed its determination that OMIDRIA receive separate payment when used in ASCs, and our MASP-3 inhibitor OMS906 is successfully advancing through its Phase 1 clinical trial. Several other important milestones should reach resolution in the near term – FDA's decision on our pending BLA for narsoplimab in the treatment of patients with TA-TMA, results from narsoplimab in the COVID-19 I-SPY platform clinical trial, and the outcome of the NOPAIN Act, which, if enacted by Congress, would mandate Medicare separate payment for non-opioid surgical pain management drugs like OMDRIA not only in ASCs but also in hospital outpatient departments. The remainder of our pipeline also pressed ahead, including the GPR174 program, the core of our immuno-oncology platform – a platform that has expanded beyond GPR174 with new CAR-T and adoptive cellular therapy programs. Omeros' momentum is building, and we look forward to seeing what the rest of the year brings."

**Second Quarter and Recent Developments**

- Recent developments regarding OMIDRIA include the following:

    - In July 2021, the Centers for Medicare and Medicaid Services (CMS) released its Outpatient Prospective Payment System (OPPS) and ASC Payment System proposed rule for calendar year 2022, which

reaffirmed its earlier decision that OMIDRIA, when used in the ASC setting, qualifies for separate payment under CMS' policy regarding non-opioid pain management surgical drugs. This policy has been in effect since 2019.

- 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 severely ill COVID-19 patients, include the following:
    - Omeros announced data from the second cohort of 10 critically ill COVID-19 patients treated with narsoplimab under compassionate use in Bergamo, Italy.
        - All of the patients had comorbidities and/or risk factors for poor outcomes, were mechanically ventilated, and had failed other therapies, including steroids.
        - 90 percent of the patients were intubated prior to initiation of narsoplimab treatment.
        - 80 percent of the patients recovered, survived and were discharged. The two deaths involved a 76-year-old who died of complications related to his pre-existing cardiomyopathy and a 68-year-old who began narsoplimab treatment after 13 days of intubation.
    - A manuscript from the Omeros-Cambridge Center for Complement and Inflammation Research (OC3IR) on the inhibition of the lectin pathway and MASP-2 as a potential treatment for severe COVID-19 was published in the peer-reviewed journal *Frontiers in Immunology*.
    - An abstract on the pharmacokinetic and pharmacodynamic modeling of lectin pathway inhibition by narsoplimab was accepted for presentation at the 16th International Symposium on IgA nephropathy.
- Updates regarding Omeros' other development programs and platforms include the following:
    - Omeros announced preliminary results from the Phase 1 clinical trial evaluating the pharmacokinetics/pharmacodynamics (PK/PD) and safety of OMS906 in healthy subjects. OMS906 inhibits MASP-3, the key activator of the alternative pathway of complement. MASP-3 is responsible for the conversion of pro-factor D to mature factor D. Data from the first five cohorts of the trial's single-ascending dose stage show that (i) OMS906 was well tolerated at all doses tested (up to 5 mg/kg) and (ii) a single 3 mg/kg intravenous dose of OMS906 and a single dose of the lowest subcutaneous concentration tested each suppressed mature complement factor D below minimum detectable levels. The human PK/PD data were consistent with once-monthly or less frequent subcutaneous dosing. Following completion of the single- and multiple-ascending dose stages of the Phase 1 trial, Omeros plans to initiate a Phase 2 clinical trial.
    - A paper detailing the mechanism of action of PDE7 inhibition in nicotine addiction was published in the peer-reviewed *Journal of Neuroscience* and was selected for inclusion in the journal's Featured Research page. Omeros has completed a successful Phase 1 trial with the lead compound in its PDE7 inhibitor program.

**Financial Results**

For the second quarter of 2021, OMIDRIA revenues were $28.8 million compared to $21.1 million for the first quarter.

Total costs and expenses for the second quarter of 2021 were $52.8 million compared to $51.7 million for the first quarter. The increase was primarily due to increased selling, general and administrative expenses in preparation for the anticipated U.S. launch of narsoplimab and additional employee-related costs. Research and development costs decreased quarter over quarter due to the timing of narsoplimab manufacturing related costs, which are expensed rather than included as inventory until the initial marketing approval for narsoplimab is certain.

For the three months ended June 30, 2021, Omeros reported a net loss of $28.6 million, or $0.46 per share, which included non-cash expenses of $3.9 million, or $0.06 per share. This compares to a net loss in the previous quarter 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 June 30, 2021, the company had $73.7 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 $50.0 million and 85 percent of eligible accounts receivable less certain reserves. Omeros also has an “at the market” program in place that 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 4195376. 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 4195376.

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. 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 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.

**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, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Revenue: | | | | |
| Product sales, net | $ 28,823 | $ 13,530 | $ 49,885 | $ 37,067 |
| | | | | |
| Costs and expenses: | | | | |
| Cost of product sales | 342 | 147 | 606 | 414 |
| Research and development | 30,937 | 24,132 | 64,309 | 53,043 |
| Selling, general and administrative | 21,560 | 16,931 | 39,598 | 34,967 |
| Total costs and expenses | 52,839 | 41,210 | 104,513 | 88,424 |
| Loss from operations | (24,016) | (27,680) | (54,628) | (51,357) |
| Interest expense | (4,910) | (5,978) | (9,808) | (11,880) |
| Other income | 333 | 364 | 753 | 912 |
| Net loss | $ (28,593) | $ (33,294) | $ (63,683) | $ (62,325) |
| Comprehensive loss | $ (28,593) | $ (33,294) | $ (63,683) | $ (62,325) |
| Basic and diluted net loss per share | $ (0.46) | $ (0.61) | $ (1.02) | $ (1.14) |
| Weighted-average shares used to compute basic and diluted net loss per share | 62,373,521 | 54,513,337 | 62,154,714 | 54,406,575 |

**OMEROS CORPORATION**
**UNAUDITED CONSOLIDATED BALANCE SHEET DATA**
**(In thousands)**

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 73,658 | $ 134,953 |
| Working capital | 64,704 | 114,549 |
| Restricted investments | 1,054 | 1,055 |
| Total assets | 145,391 | 181,042 |
| Total current liabilities | 47,697 | 36,736 |
| Lease liabilities | 36,279 | 32,552 |
| Unsecured convertible senior notes, net | 312,585 | 236,288 |
| Accumulated deficit | (941,052) | (872,672) |
| Total shareholders' deficit | (246,296) | (120,752) |