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): March 1, 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 March 1, 2021, Omeros Corporation issued a press release announcing financial results for the three months and year ended December 31, 2020. 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 March 1, 2021, pertaining to Omeros Corporation's financial results for the three months and year ended December 31, 2020.
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: March 1, 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 Fourth Quarter and Year-End 2020 Financial Results

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

SEATTLE, WA – March 1, 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, complement-mediated diseases, disorders of the central nervous system and immune-related diseases, including cancers, today announced recent highlights and developments as well as financial results for the fourth quarter and year ended December 31, 2020, which include:

- Revenues for the fourth quarter of 2020 were $10.6 million compared to $26.1 million in the third quarter of 2020. The decrease from the prior period is primarily due to the expiration, on October 1, 2020, of pass-through reimbursement for OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%. In December, the Centers for Medicare and Medicaid Services (CMS) confirmed that OMIDRIA qualifies for separate payment, effective retroactively as of October 1, 2020, when used in the ASC setting under its policy for non-opioid pain management surgical drugs.

- Full year 2020 OMIDRIA revenues were $73.8 million, compared to $111.8 million in the prior year. The decrease was due to the reduction in cataract surgeries performed as a result of the COVID-19 pandemic and uncertainty regarding Medicare Part B reimbursement for OMIDRIA after its pass-through status expired on October 1, 2020.

- At December 31, 2020, the company had cash, cash equivalents and short-term investments available for operations of $135.0 million.

- Omeros' Biologics License Application (BLA) for narsoplimab was accepted and granted priority review by the U.S. Food and Drug Administration (FDA) for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA or TA-TMA). The Prescription Drug User Fee Act (PDUFA) date is July 17, 2021.

- Narsoplimab entered the I-SPY COVID-19 platform trial sponsored by Quantum Leap Healthcare Collaborative, which is evaluating drugs and investigational products for the treatment of critically ill COVID-19 patients. Narsoplimab is the only complement inhibitor invited to participate in this trial.

- Initial data are expected next quarter from the Phase 1 clinical trial evaluating the pharmacokinetics, pharmacodynamics, safety and tolerability of OMS906, the company's inhibitor of MASP-3, the key activator of the alternative pathway of complement.

"2020 was a challenging year for everyone, but our team's list of accomplishments is impressive – submission of the BLA for transplant-associated TMA and life-saving treatment of critically ill COVID-19 patients with narsoplimab, reinstatement of separate payment for our ophthalmic product OMIDRIA, entry into the clinic for our MASP-3 inhibitor OMS906, and the addition of substantial working capital to our balance sheet," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "As we entered the new year, the team maintained its momentum, continuing to build on these achievements. The BLA was granted priority review and our commercial launch plan is on track to bring narsoplimab to patients as soon as we receive approval. The only complement inhibitor in the I-SPY COVID-19 trial, narsoplimab is the focus of growing attention from international government agencies and global organizations in the fight against COVID, and we are advancing the drug across IgA nephropathy, aHUS and an

expanding set of indications. Once again secured, OMIDRIA revenues are increasing and will continue to provide working capital to fund our pipeline, including OMS906, which remains on schedule to read out initial data next quarter, and the rest of our programs. 2021 has started strong, and we expect that it will finish even stronger."

Fourth Quarter and Recent Developments

- Narsoplimab is Omeros' lead antibody targeting MASP-2 to inhibit activation of the lectin pathway of complement and is under review by FDA for the treatment of TA-TMA and is in Phase 3 clinical programs in immunoglobulin A (IgA) nephropathy, atypical hemolytic uremic syndrome (aHUS) and critically ill COVID-19 patients. Recent narsoplimab-related developments include the following:

    - FDA accepted and granted priority review to the BLA for narsoplimab for the treatment of TA-TMA and set a PDUFA date of July 17, 2021. FDA also indicated in its filing letter that FDA is not currently planning to hold an advisory committee meeting to discuss the BLA. Priority review is granted to applications for therapies that, if approved, would be significant improvements in the safety or effectiveness of the treatment, prevention or diagnosis of serious conditions.

    - Omeros completed the application for a New Technology Add-On Payment (NTAP) for narsoplimab, which, if granted, would provide for special payment to hospitals for narsoplimab when administered in the hospital inpatient setting. The NTAP interim rule is expected in the second quarter of 2021. As part of our reimbursement efforts, we applied, and received preliminary support from CMS, for ICD-10 procedural and diagnostic codes in connection with the use of narsoplimab in the treatment of TA-TMA.

    - At the 2020 American Society of Hematology Annual Meeting, Omeros made a presentation directed to the pharmacodynamics of narsoplimab in humans and primates, which subsequently was published in the peer-reviewed journal *Blood*.

    - Omeros also had a significant presence at the 2021 Annual Meeting of the American Society of Transplantation and Cellular Therapy in February, including a podium presentation by Dr. Samer Khaled of City of Hope on the pivotal clinical trial results with narsoplimab in TA-TMA.

    - Narsoplimab entered the I-SPY COVID-19 platform trial, which is evaluating drugs and investigational products for the treatment of critically ill COVID-19 patients. Narsoplimab is the only complement inhibitor invited to participate in this trial. The trial utilizes Quantum Leap Healthcare Collaborative's adaptive platform trial design, which is intended to increase trial efficiency by minimizing the number of participants and time required to evaluate potential treatments.

    - Omeros has continued treating COVID-19 patients with narsoplimab under compassionate use – to date, nine more in Bergamo, Italy and four in the U.S. All of these patients prior to receiving narsoplimab were severely ill, intubated, had multiple comorbidities, and had failed other therapies, including anti-virals, targeted anti-inflammatory therapeutics, convalescent plasma and steroids. Following treatment with narsoplimab, the laboratory improvements and clinical outcomes of these patients are consistent with those seen in the initial cohort of Bergamo patients and published in *Immunobiology*. A manuscript detailing the findings and clinical outcomes of the second cohort of patients is in preparation.

- Recent developments regarding Omeros' ophthalmic drug OMIDRIA include the following:

    - In December 2020, CMS confirmed that OMIDRIA qualifies for separate payment in the ASC setting under its policy for non-opioid pain management surgical drugs, effective retroactively from October 1, 2020, when pass-through reimbursement for OMIDRIA expired.

    - A new study showing that OMIDRIA significantly decreases retinal thickness and macular edema caused by cataract surgery has been selected for a podium presentation at the 2021 Congress of American Society of Cataract and Refractive Surgery in August. This study further confirms previously published clinical data showing that OMIDRIA significantly reduces the incidence of sight-threatening cystoid macular edema while precluding the need for perioperative steroids.

- Updates regarding Omeros' other development programs and platforms include the following:

    - Initial data are expected next quarter from the Phase 1 clinical trial evaluating OMS906, the company's inhibitor of MASP-3, the key activator of the alternative pathway of complement. The placebo-controlled, double-blind, single-ascending-dose and multiple-ascending-dose trial is assessing the pharmacokinetics, pharmacodynamics, safety and tolerability of OMS906. Omeros has completed all of the intravenous dosing cohorts in the single ascending dose study and expects to begin subcutaneous dosing this month.

Financial Results

Fourth Quarter 2020

For the fourth quarter of 2020, OMIDRIA revenues were $10.6 million. This compares to OMIDRIA revenues of $26.1 million for the third quarter of 2020. The decrease was primarily due to the expiration of pass-through reimbursement for OMIDRIA on October 1, 2020 and the uncertainty around separate payment for OMIDRIA until CMS confirmed in December that OMIDRIA qualifies for separate payment when used in the ASC setting under CMS' policy for non-opioid pain management surgical drugs.

Total costs and expenses for the fourth quarter of 2020 were $44.4 million, compared to $51.5 million in the preceding quarter. The decrease was primarily due to a technology license payment related to the OMS906 program in that earlier quarter.

For the three months ended December 31, 2020, Omeros reported a net loss of $37.3 million, or $0.60 per share, which included non-cash expenses of $3.5 million, or $0.06 per share. This compares to the prior year fourth quarter, when Omeros reported a net loss of $29.2 million or $0.58 per share, which included non-cash expenses of $6.3 million, or $0.12 per share.

As of December 31, 2020, Omeros had $135.0 million of cash, cash equivalents and short-term investments available for operations.

Full Year 2020

Revenues for 2020 were $73.8 million compared to $111.8 million for 2019. The decrease was due to the reduction in cataract surgeries performed due to the COVID-19 pandemic and the uncertainty regarding Medicare Part B reimbursement for OMIDRIA after its pass-through status expired on October 1, 2020. In December 2020, CMS confirmed separate payment for OMIDRIA in the ASC setting effective retroactively as of October 1.

For the year ending December 31, 2020, total costs and expenses were $184.4 million, compared to $175.2 million in the prior year.

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 4:30 p.m. Pacific Time; 1:30 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 3399452. 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 (855) 859-2056 from the United States and Canada or (404) 537-3406 internationally. The replay passcode is 3399452.

To access the live or subsequently archived webcast of the conference call on the internet, go to the company's website at www.omeros.com and select "Events" under the Investors section of the website. To access the live webcast, please connect to the website at least 15 minutes prior to the call to allow for any software download that may be necessary.

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, complement-mediated diseases, disorders of the central nervous system and immune-related diseases, including cancers. 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, 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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenue:				
Product sales, net	$ 10,632	$ 33,417	$ 73,813	$ 111,805
Costs and expenses:				
Cost of product sales	87	401	902	865
Research and development	26,458	40,588	110,817	109,696
Selling, general and administrative	17,903	16,132	72,695	64,626
Total costs and expenses	44,448	57,121	184,414	175,187
Loss from operations	(33,816)	(23,704)	(110,601)	(63,382)
Loss on early extinguishment of debt	—	—	(13,374)	—
Interest expense	(7,988)	(5,811)	(26,751)	(22,657)
Other income	374	290	654	1,553
Loss before income taxes	(41,430)	(29,225)	(150,072)	(84,486)
Income tax benefit	4,157	—	12,011	—
Net loss	$ (37,273)	$ (29,225)	$ (138,061)	$ (84,486)
Comprehensive loss	$ (37,273)	$ (29,225)	$ (138,061)	$ (84,486)
Basic and diluted net loss per share	$ (0.60)	$ (0.58)	$ (2.41)	$ (1.71)
Weighted-average shares used to compute basic and diluted net loss per share	61,659,835	58,233,988	57,176,743	49,523,444

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	December 31, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 134,953	$ 60,788
Working capital	114,549	48,286
Restricted investments	1,055	1,154
Total assets	181,042	136,969
Total current liabilities	36,736	55,459
Lease liability	32,552	35,822
Unsecured convertible senior notes, net	236,288	158,213
Accumulated deficit	(872,672)	(734,611)
Total shareholders' deficit	(120,752)	(109,021)