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 11, 2020

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 11, 2020, Omeros Corporation issued a press release announcing financial results for the three months ended March 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 May 11, 2020, pertaining to Omeros Corporation's financial results for the three months ended March 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: May 11, 2020

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

Omeros Corporation Reports First Quarter 2020 Financial Results

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

SEATTLE, WA – May 11, 2020 – 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 first quarter ended March 31, 2020, which include:

- Revenues for the first quarter of 2020 were $23.5 million, compared to $21.8 million and $33.4 million in the first and fourth quarters of 2019, respectively. The decrease from the fourth quarter of 2019 reflects the COVID-19-related postponement of cataract procedures by ASCs and hospitals in early March.

- Net loss in the first quarter of 2020 was $29.0 million, or $0.53 per share, including non-cash expenses of $6.4 million, or $0.12 per share. This compares to a net loss of $24.3 million, or $0.50 per share, which included non-cash expenses of $6.0 million, or $0.12 per share, for the comparable quarter in 2019.

- At March 31, 2020, Omeros had cash, cash equivalents and short-term investments available for operations of $54.0 million, a decrease of $6.8 million from December 31, 2019.

- Omeros submitted the second part of its rolling biologics license application (BLA) for narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). The submission was on schedule and consisted of information relating to the chemistry, manufacturing and controls (CMC) of narsoplimab.

“I am immensely proud of how Omeros’ employees have responded to the unprecedented challenges presented by the global pandemic, adapting to a changing work environment while continuing to meet program milestones with the same commitment, sense of urgency and level of productivity,” said Gregory A. Demopulos, M.D., Omeros’ chairman and chief executive officer. “We already are seeing rapid resumption of OMIDRIA purchases by ASCs and hospitals as they reopen and begin addressing the backlog of cataract surgery patients. For narsoplimab, we just submitted the second part of our rolling BLA as scheduled and continue to target next quarter for its completion. Our ongoing and upcoming clinical programs have weathered COVID-19 well, and we continue to target the start of our OMS906 clinical program next month and data readout from our ARTEMIS-IGAN trial next year. Our research laboratories and nonclinical functions have also remained fully operational. Our preparations for the commercial launch of narsoplimab have accelerated and, with the addition of recent hires, we continue to build top-tier sales, marketing and medical affairs teams. We look forward to adding narsoplimab to what we expect will be a long line of commercial products.”

First Quarter and Recent Developments

- Recent developments regarding OMIDRIA include the following:

    - Previously reported peer-reviewed published data demonstrate that OMIDRIA significantly reduces the need for intraoperative fentanyl, a potent and highly addictive opioid, while significantly decreasing pain scores. A separate study to assess the effect of OMIDRIA on use of postoperative opioid use was also recently completed. In that study an analysis of claims data over a 3-year period was performed by IBM Watson Health. Claims data were evaluated from 218,672 patients 65 years of age or older who

underwent cataract surgery. All patients were required to have no opioid use during the 6 months prior to surgery. Filled opioid prescriptions in the OMIDRIA-treated group were compared to those in the non-OMIDRIA-treated group. Patients who received OMIDRIA during surgery received fewer opioid pills in the 2 days and 7 days post-surgery than patients who did not receive OMIDRIA. The median reductions seen were 56 percent (20 pills versus 45 pills) at 2 days ($p = 0.015$) and 33 percent (40 pills versus 60 pills) at 7 days ($p = 0.029$). These data provide further evidence that OMIDRIA not only reduces the need for intraoperative fentanyl but also decreases the use of postoperative opioids.

- The results of a retrospective study of the incidence of postoperative clinical cystoid macular edema (CME), breakthrough iritis, pain and photophobia in patients receiving OMIDRIA were published in the peer-reviewed *Journal of Cataract and Refractive Surgery*. The study demonstrated with statistical significance that patients receiving OMIDRIA had lower incidences of clinical CME ($p = 0.021$), breakthrough iritis ($p = 0.001$) and pain ($p = 0.001$) compared to a control group receiving conventional perioperative steroids. Patients receiving OMIDRIA also had lower incidence of photophobia, though not statistically significant.

- A manuscript on the safety and efficacy of OMIDRIA for pediatric cataract surgery was also published by *Journal of Cataract and Refractive Surgery*. The randomized double-blind study in children undergoing cataract surgery showed that OMIDRIA is safe to use in children and resulted in lower pain scores for patients receiving OMIDRIA than for the control group. As a result, the FDA-approved label for OMIDRIA has no age restriction

- Recent developments regarding narsoplimab, Omeros' lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2) in Phase 3 clinical programs for the treatment of HSCT-TMA, Immunoglobulin A (IgA) nephropathy, and atypical hemolytic uremic syndrome (aHUS), include the following:

  - Omeros submitted the second part of its rolling BLA for narsoplimab for the treatment of HSCT-TMA, consisting of CMC-related information, including data on manufacturing, analytical procedures, and associated method validations.

  - A manuscript authored by a group from the University of Leicester led by Dr. Jonathan Barratt PhD, FCRP, Professor of Renal Medicine, has been accepted for peer-reviewed publication. The manuscript describes the beneficial effects of narsoplimab in IgA vasculitis-associated nephritis, a rapidly progressive glomerulonephritis. A second manuscript presenting Omeros' IgA nephropathy Phase 2 clinical data and authored by the company's IgA nephropathy Academic Leadership Committee, which is comprised of international thought leaders, has also undergone journal review and is expected to be published soon.

  - Consistent with FDA guidelines and recommendations of the independent data safety monitoring committee regarding ongoing clinical trials during the COVID-19 pandemic, study sites for Omeros' ongoing Phase 3 programs for narsoplimab in IgA nephropathy and aHUS are conducting trials in a manner consistent with local recommendations and/or regulations to maintain safety of study patients. As a result, at some sites, new patient enrollment has slowed while previously enrolled patients are continuing in the trials. We continue targeting data readout for the IgA nephropathy trial next year.

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

  - First-in-human-enabling toxicology studies for the company's MASP-3 inhibitor OMS906 are complete. Omeros is on track to file a clinical trial application this quarter and to begin dosing in the first part of the third quarter.

  - As part of the strategy for life-cycle management of the company's complement franchise, Omeros continues to develop a longer-acting second generation antibody against MASP-2, which is targeted to enter the clinic in early 2022, to be followed by an orally available small molecule inhibitor against MASP-2 also under development.

Financial Results

For the first quarter of 2020, revenues, all related to sales of OMIDRIA, were $23.5 million, compared to $21.8 million for the same period in 2019 and a record-high $33.4 million for the fourth quarter of 2019. The decrease from the prior quarter reflects declining sales beginning in early March as a result of inventory utilization by ASCs and hospitals in anticipation of the COVID-19-related shutdown of elective surgical procedures, which occurred in mid-March. Sales of OMIDRIA to wholesalers were minimal in March. March typically accounts for about 45 percent of total first-quarter OMIDRIA revenues, and Omeros realized only one week of March revenues. In early May, a large number of states began re-opening ASCs and hospitals to cataract surgery, and facilities in at least 36 states have already initiated re-ordering of OMIDRIA from wholesalers

Total costs and expenses for the first quarter of 2020 were $47.2 million compared to $41.0 million for the comparable period in 2019. The increase was due to increased research and development and pre-commercialization marketing activities for narsoplimab.

For the three months ended March 31, 2020, Omeros reported a net loss of $29.0 million, or $0.53 per share, which included non-cash expenses of $6.4 million, or $0.12 per share. This compares to a net loss of $24.3 million, or $0.50 per share, which included non-cash expenses of $6.0 million, or $0.12 per share, for the comparable quarter in 2019.

As of March 31, 2020, the company had $54.0 million of cash, cash equivalents and short-term investments available for operations, a decrease $6.8 million from December 31, 2019. The company also has a line of credit, which permits borrowing up to the lesser of 85 percent of eligible accounts receivable and $50 million. As of March 31, 2020, the eligible accounts receivable balance was $24.1 million, and Omeros has not borrowed under this facility.

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 6549035. 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 6549035.

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 an innovative biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting complement-mediated diseases, disorders of the central nervous system and immune-related diseases, including cancers. In addition to its commercial drug OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%, Omeros has multiple Phase 3 and Phase 2 clinical-stage development programs focused on complement-mediated disorders and substance abuse, as well as a diverse group of preclinical programs including GPR174, a novel target in immuno-oncology that modulates a new cancer immunity axis recently discovered by Omeros. Small-molecule inhibitors of GPR174 are part of Omeros' proprietary G protein-coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and their corresponding compounds. The company also exclusively possesses a novel antibody-generating platform.

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 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 2, 2020, as supplemented by our Quarterly Report on Form 10-Q filed with the SEC on May 11, 2020 and subsequent filings with the SEC. 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, even if new information becomes available in the future.

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

	Three Months Ended March 31,	
	2020	2019
Revenue:		
Product sales, net	$ 23,537	$ 21,779
Costs and expenses:		
Cost of product sales	267	131
Research and development	28,911	26,255
Selling, general and administrative	18,036	14,632
Total costs and expenses	47,214	41,018
Loss from operations	(23,677)	(19,239)
Interest expense	(5,903)	(5,600)
Other income	549	494
Net loss	$ (29,031)	$ (24,345)
Comprehensive loss	$ (29,031)	$ (24,345)
Basic and diluted net loss per share	$ (0.53)	$ (0.50)
Weighted-average shares used to compute basic and diluted net loss per share	54,299,813	49,014,009

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	March 31, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 53,980	$ 60,788
Working capital	27,675	48,286
Restricted investments	1,154	1,154
Total assets	118,214	136,969
Total current liabilities	57,936	55,459
Lease liability	34,993	35,822
Convertible Senior Notes	160,746	158,213
Accumulated deficit	(763,642)	(734,611)
Total shareholders' deficit	(131,864)	(109,021)