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 2, 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 March 2, 2020, Omeros Corporation issued a press release announcing financial results for the three months and year ended December 31, 2019. 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 2, 2020, pertaining to Omeros Corporation's financial results for the three months and year ended December 31, 2019.

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 2, 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 Fourth Quarter and Year-End 2019 Financial Results

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

SEATTLE, WA – March 2, 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 fourth quarter and year ended December 31, 2019, which include:

- 4Q 2019 OMIDRIA® revenues were $33.4 million, Omeros' highest revenue quarter to date and representing another quarter of double-digit growth of 12 percent compared to 3Q 2019.

- Full year 2019 OMIDRIA revenues were $111.8 million, a 274 percent increase from the prior year.

- Net loss in 4Q 2019 was $29.2 million, or $0.58 per share. Net loss for the full year 2019 was $84.5 million, or $1.71 per share. Non-cash expenses for the fourth quarter and the full year of 2019 were $6.3 million, or $0.12 per share, and $24.8 million, or $0.50 per share, respectively. Included in both 4Q and full year net loss is $12.6 million, or $0.25 per share, in connection with Omeros' election to accelerate the manufacturing schedule for a one-time set of five narsoplimab process validation and commercial lots. These lots were successfully manufactured, provide data to satisfy the BLA process validation requirements, and can be used for commercial sales following approval.

- At December 31, 2019, the company had cash, cash equivalents and short-term investments available for operations of $60.8 million.

- Data from the narsoplimab pivotal registration trial met the FDA-agreed primary efficacy endpoint, with complete response rates of 54 percent ($p<0.0001$) in all patients receiving at least one dose of narsoplimab and 65 percent ($p<0.0001$) in all patients receiving at least the protocol-specified four weeks of dosing, well surpassing the FDA-agreed threshold for efficacy of 15 percent

  On the secondary endpoint of 100-day survival, 68 percent of all patients receiving at least one dose of narsoplimab achieved 100-day survival, with 83 percent of patients receiving at least the protocol-specified four weeks of dosing and 93 percent of responders achieving the endpoint. Experts familiar with the pivotal trial data would expect a 100-day survival rate of less than 20 percent in this population.

"2019 was a year of tremendous accomplishment for Omeros," stated Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "Our pivotal trial in HSCT-TMA generated data that substantially surpass FDA's agreed threshold for efficacy and enabled submission of the first sections of our rolling BLA, OMIDRIA delivered record annual sales of $112 million, and we discovered a cancer immunity axis controlled by GPR174, a target that we control and expect could change the immuno-oncology landscape. And 2020 is shaping up to be an even better year. We are on track to complete submission of the narsoplimab BLA for HSCT-TMA and look forward to FDA's review and approval as we move the drug toward two additional indications in IgA nephropathy and aHUS. We expect that 2020 will also bring continued growth in OMIDRIA sales, further clinical development of our OMS527 addiction program, a Phase 1 trial for our MASP-3 inhibitor OMS906, and ongoing progress with our MASP-2 small-molecule inhibitor and next-generation antibody as well as our GPR174 antagonists, driving them toward the clinic. We've built a top-tier group of first-in-kind

assets, are delivering on their promise, and expect that they will significantly improve the lives of patients and their families."

Fourth Quarter and Recent Developments

- 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 hematopoietic stem-cell transplant-associated thrombotic microangiopathy (HSCT-TMA), Immunoglobulin A (IgA) nephropathy, and atypical hemolytic uremic syndrome (aHUS), include the following:

    - Omeros recently announced positive data across primary and secondary endpoints in its pivotal trial of narsoplimab in HSCT-TMA patients.

        - The primary endpoint is a set of rigorous response criteria requiring improvements in HSCT-TMA laboratory markers and improvement in clinical status. The FDA-agreed threshold for the efficacy primary endpoint in the very sick patient population treated in this trial is a response rate of 15 percent. Across all patients receiving at least one dose of narsoplimab, 54 percent ($p<0.0001$) were complete responders; in patients receiving at least the protocol-specified four weeks of narsoplimab treatment, the complete response rate was 65 percent ($p<0.0001$).

        - The secondary endpoints include survival rates and change from baseline in laboratory markers. The 100-day survival rate was 68 percent in all patients who received at least one dose of narsoplimab, 83 percent in patients who received at least the protocol-specified 4 weeks of narsoplimab treatment, and 93 percent in responders. Experts familiar with the pivotal trial data would expect a 100-day survival rate of less than 20 percent in this population. Across all patients, statistically significant improvement was seen in platelet count and LDH and haptoglobin levels ($p<0.01$ for each marker).
        - The most commonly reported adverse events in the trial were diarrhea, nausea, vomiting, hypokalemia, neutropenia and fever – all common in stem-cell transplant patients. Six deaths also occurred during the trial and were due to sepsis, progression of the underlying disease and graft-versus-host disease. All of these are common causes of death in this patient population.

    - In February 2020, Omeros met with FDA to discuss the chemistry, manufacturing and controls aspects of the Biologics License Application (BLA) for narsoplimab in HSCT-TMA. At the meeting, FDA requested near-term manufacturing dates for narsoplimab so that FDA's pre-approval inspections could be scheduled. FDA and Omeros also reached agreement on requirements for stability data and release assays for the BLA

    - Data from the narsoplimab pivotal trial in HSCT-TMA were presented and discussed by a panel of international experts in hematopoietic stem-cell transplantation at a recent continuing medical education symposium held at the Transplant and Cellular Therapy Conference in Orlando.

    - Omeros initiated a collaboration with myTomorrows, a global health technology company, to broaden its expanded access program to support international availability of narsoplimab to eligible patients who have no other treatment options.

    - The ARTEMIS-IGAN Phase 3 clinical trial for narsoplimab in IgA nephropathy is ongoing at 91 sites in the U.S. and internationally, with additional sites coming on line. Data readout is expected next year.

    - Multiple manuscripts directed to narsoplimab in IgA nephropathy have been accepted for publication or are under review by peer-reviewed journals. Most recently, a review article entitled "MASP-2 Inhibition as Potential Strategy for IgA Nephropathy Management" authored by Drs. Jonathan Barratt of University of Leicester and Richard Lafayette of Stanford University was accepted for publication in the journal *Drugs of the Future*.

- Recent developments regarding OMIDRIA include the following:
    - The Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act was introduced in the both the U.S. House of Representatives and the U.S. Senate during the fourth quarter. The proposed legislation has strong bipartisan backing in both chambers of Congress and is supported by a diverse group of grassroots organizations. If passed, the legislation would mandate separate payment by Centers for Medicare and Medicaid Services (CMS) for a period of five years for non-opioid pain treatments used during surgery, like OMIDRIA.
    - The new product-specific permanent J-code for OMIDRIA became effective on October 1, 2019. J-codes standardize the submission and payment of insurance claims across Medicare, Medicare Advantage, Medicaid and commercial insurance plans.
- Updates regarding Omeros' other development programs and platforms include the following:
    - Omeros' MASP-3 inhibitor OMS906 is on track for clinical entry in June of this year. Initially targeting paroxysmal nocturnal hemoglobinuria (PNH), OMS906 is expected to allow monthly subcutaneous dosing.
    - Following positive results from the Phase 1 study, Omeros is planning for a Phase 2 trial of its phosphodiesterase 7 inhibitor OMS527 in nicotine addiction.
    - In the fourth quarter of 2019, Omeros presented new data on its GPR174 immuno-oncology program at international medical congresses. Data from human *ex vivo* studies demonstrate that GPR174 inhibition results in downregulation of checkpoint and tumor-promoting factors. In addition, data from animal models reveal enhanced anti-tumor immune responses in GPR174-deficient mice and synergism between adenosine receptor antagonists and GPR174 antagonists in promoting interleukin-2 (IL-2) and interferon-γ (IFN-γ) production from human T cells. Omeros discovered a cancer-immunity axis controlled by GPR174 and is building an exclusive intellectual property position directed to modulation of GPR174 for the treatment of cancer.
- In December 2019, Omeros raised $54.2 million in net proceeds in an underwritten offering of common stock.

Financial Results

Fourth Quarter 2019

For the quarter ended December 31, 2019, revenues were $33.4 million, all relating to sales of OMIDRIA. This compares to OMIDRIA revenue of $22.0 million for the same period in 2018. On a sequential quarter-over-quarter basis, OMIDRIA revenue increased by $3.6 million or 12 percent. The increases from the prior year and from the prior quarter are primarily due to a growing number of purchasing accounts as well as deeper penetration within accounts across hospitals, ambulatory surgery centers and government payers.

Total operating costs and expenses for the quarter ended December 31, 2019 were $57.1 million compared to $40.5 million for the comparable period in 2018 and $41.0 million in the preceding quarter. The increase in both cases primarily reflects $12.6 million of expenses incurred ahead of schedule due to Omeros' election to accelerate the manufacturing schedule for a one-time set of five narsoplimab process validation and commercial lots. These lots were successfully manufactured, provide data to satisfy the BLA process validation requirements, and can be used for commercial sales following approval.

For the three months ended December 31, 2019, Omeros reported a net loss of $29.2 million or $0.58 per share, which included non-cash expenses of $6.3 million ($0.12 per share) and the aforementioned manufacturing expenses of $12.6

million ($0.25 per share). This compares to the prior year's fourth quarter when Omeros reported a net loss of $23.5 million, or $0.48 per share, which included non-cash expenses of $4.9 million ($0.10 per share).

Full Year 2019

Revenues for the full year 2019 were $111.8 million compared to $29.9 million for full year 2018. The significant increase year-over-year is primarily due to the status of pass-through reimbursement. During the period January 1, 2018 to September 30, 2018, OMIDRIA was not reimbursed separately under Medicare Part B. This had a significant negative impact on revenues during 2018. Following reinstatement of pass-through reimbursement on October 1, 2018, OMIDRIA revenues quickly returned to and exceeded previous levels.

For the year ending December 31, 2019, total costs and expenses were $175.2 million compared to $142.1 million in the prior year. The increase for the current year compared to the prior year is due primarily to the additional narsoplimab manufacturing, an increase in spending on preclinical research and development in our OMS906 program and the resumption of OMIDRIA marketing activities following reinstatement of pass-through reimbursement on October 1, 2018.

At December 31, 2019, the company had cash, cash equivalents and short-term investments available for operations of $60.8 million and an accounts receivable balance of $35.2 million. The company also has an accounts receivable-based line of credit which permits borrowing up to the lesser of $50.0 million and 85 percent of eligible accounts receivable, subject to applicable reserves. We have 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 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 4870947. 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 4870947.

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, 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 on March 2, 2020. 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 December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Product sales, net	$ 33,417	$ 22,017	$ 111,805	$ 29,868
Costs and expenses:				
Cost of product sales	401	157	865	512
Research and development	40,588	25,446	109,696	89,860
Selling, general and administrative	16,132	14,888	64,626	51,718
Total costs and expenses	57,121	40,491	175,187	142,090
Loss from operations	(23,704)	(18,474)	(63,382)	(112,222)
Loss on early extinguishment of debt	—	(12,993)	—	(12,993)
Interest expense	(5,811)	(5,149)	(22,657)	(16,252)
Other income	290	153	1,553	1,781
Loss before income taxes	(29,225)	(36,463)	(84,486)	(139,686)
Income tax benefit	—	12,929	—	12,929
Net loss	$ (29,225)	$ (23,534)	$ (84,486)	$ (126,757)
Basic and diluted net loss per share	$ (0.58)	$ (0.48)	$ (1.71)	$ (2.61)
Weighted-average shares used to compute basic and diluted net loss per share	50,622,516	48,029,195	49,523,444	48,582,636

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	December 31, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 60,788	$ 60,498
Working capital	48,286	52,511
Restricted investments	1,154	1,154
Total assets	136,969	95,936
Total current liabilities	55,459	37,356
Lease liability	35,822	2,467
Unsecured convertible senior notes, net	158,213	148,981
Accumulated deficit	(734,611)	(650,125)
Total shareholders' deficit	(109,021)	(100,156)