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 10, 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 August 10, 2020, Omeros Corporation issued a press release announcing financial results for the three and six months ended June 30, 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 August 10, 2020, pertaining to Omeros Corporation's financial results for the three and six months ended June 30, 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: August 10, 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 Second Quarter 2020 Financial Results

SEATTLE, WA – August 10, 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 second quarter ended June 30, 2020, which include:

- Revenues for the second quarter of 2020 were $13.5 million, compared to $26.8 million in the second quarter of 2019 and $23.5 million in the first quarter of 2020. The decreases reflect the impact of the postponement of cataract procedures by ASCs and hospitals due to COVID-19. Cataract surgery resumed beginning in the second half of May 2020, and by the end of June 2020, the run rate of weekly OMIDRIA sales approximated levels seen prior to the pandemic.

- Net loss in the second quarter of 2020 was $33.3 million, or $0.61 per share. This compares to a net loss of $14.5 million, or $0.29 per share, in the second quarter of 2019. Net loss in the second quarter of 2020 included non-cash expenses of $6.9 million, or $0.13 per share.

- Six COVID-19 patients in Italy with acute respiratory distress syndrome (ARDS) were treated with narsoplimab under a compassionate use program. All patients, who initially required mechanical ventilation, recovered, survived and were discharged from the hospital. Narsoplimab treatment was associated with rapid and sustained improvement across all assessed markers of endothelial/cellular damage and/or inflammation.

- Omeros completed submission to FDA of the chemistry, manufacturing and controls (CMC) information for the Company's rolling Biologic License Application (BLA) for narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA).

- Omeros submitted a clinical trial application to European regulators and an investigational new drug application to the U.S. Food and Drug Administration (FDA) to initiate a Phase 1 clinical trial for OMS906, the company's MASP-3 inhibitor.

"The data from COVID-19 patients treated with narsoplimab clearly support the growing body of scientific literature pointing to the central role of MASP-2 and the lectin pathway in COVID-19-related lung injury," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "Narsoplimab represents the first time that a lectin pathway inhibitor has been used to treat COVID-19 and, in addition to complement inhibition, brings what appears to be a unique benefit – anticoagulant effects, which may also prove to be very important in the treatment of this disease and other endothelial injury syndromes. Discussions with U.S. government agencies are underway with the objective of expanding the availability of narsoplimab to COVID-19 patients. We are also rapidly advancing toward regulatory approval for narsoplimab in the treatment of transplant-associated TMA. We have recently completed submission of the remaining CMC portion of our rolling BLA. We are targeting this quarter for the completion of the BLA, and preparations for anticipated commercial launch are proceeding well. We also reached a key milestone in our OMS906 program, with the on-schedule submission of the clinical trial application. In addition, we filed an IND to FDA to increase the likelihood of initiating enrollment next month. I am immensely proud of our team – they've continued to adapt to the challenges imposed by COVID-19, advancing our clinical and development programs and improving the lives of patients."

Second Quarter and Recent Developments

- In response to a request from physicians in Bergamo, Italy, Omeros implemented a compassionate use program for narsoplimab to treat six COVID-19 patients with ARDS requiring continuous positive airway pressure (CPAP) or intubation prior to treatment. All narsoplimab-treated patients recovered and survived. Narsoplimab was associated with rapid and sustained reduction of circulating endothelial cell counts and concurrent reduction of serum levels of IL-6, IL-8, LDH, D-dimer and AST. Narsoplimab was well tolerated and no adverse drug reactions were reported. A retrospective comparison of two control groups with similar entry criteria and baseline characteristics showed significantly higher mortality rates, at 32 percent and 53 percent, than the narsoplimab-treated group. A manuscript detailing the results of the study has been accepted for publication in the peer-reviewed journal Immunobiology.

  Endothelial damage, which can play an early and central pathogenic role in ARDS and thrombosis, activates the lectin pathway of complement. Mannan-binding lectin-associated serine protease-2 (MASP-2), the lectin pathway's effector enzyme and the target for narsoplimab, binds the nucleocapsid protein of severe acute respiratory syndrome-associated coronavirus-2 (SARS-CoV-2) – the virus responsible for COVID-19 – resulting in complement activation and lung injury.

  Discussions are progressing between Omeros and offices in the Department of Health and Human Services, including the Biomedical Advanced Research and Development Authority (BARDA), along with the National Institutes of Health Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) program regarding potential funding to accelerate large-scale manufacturing to enable broader availability of narsoplimab for COVID-19 patients and for other COVID-19-related programmatic activities.

- Recent developments regarding narsoplimab, Omeros' lead human monoclonal antibody targeting 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:

  - In preparation for the anticipated commercial launch of narsoplimab, Omeros is working closely with the transplant community, patient advocacy groups and payers.

  - Results from the pivotal trial of narsoplimab in the treatment of HSCT-TMA will be presented at the virtual annual meeting of the European Society of Bone Marrow Transplant (EBMT) in August by Dr. Rafael Duarte, chair of the 2020 EBMT meeting.

  - Professor Alessandro Rambaldi of the University of Milan and the Director of the Department of Hematology and Oncology at the Papa Giovanni XXIII Hospital presented results from the HSCT-TMA pivotal trial at the 25th Annual Congress of the European Hematology Association in June.

  - An article authored by a group from the University of Leicester led by Dr. Jonathan Barratt PhD, FCRP, Professor of Renal Medicine, has been published in the peer-reviewed journal Drugs of the Future. The manuscript describes the beneficial effects of narsoplimab in IgA vasculitis-associated nephritis, a rapidly progressive glomerulonephritis.

  - An article titled "Inhibition of the lectin pathway of the complement system as a novel approach in the management of IgA vasculitis associated nephritis" was published in Nephron.

  - A 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 in IgA nephropathy, has been accepted for publication by the peer-reviewed journal Kidney International Reports.

- Recent developments regarding OMIDRIA include the following:

- Data from a study demonstrating the effect of OMIDRIA on reducing instances of postoperative cystoid macular edema, breakthrough iritis and pain as well as the need for postoperative topical steroids was presented at the virtual American Society of Cornea and Refractive Surgery Congress in May.

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

  - Omeros submitted a clinical trial application in June to European regulators as well as an investigational new drug application to FDA in July to initiate a Phase 1 clinical trial for OMS906, the company's MASP-3 inhibitor and currently expects to begin enrollment in the Phase 1 trial in September.

Financial Results

For the second quarter of 2020, revenues, all related to sales of OMIDRIA, were $13.5 million, down from $26.8 million for the same period in 2019 and $23.5 million for the first quarter of 2020. The decrease in the current quarter is due to ambulatory centers (ASCs) and hospitals postponing nearly all cataract surgeries from mid-March until mid-May due to the COVID-19 pandemic. Cataract surgeries resumed beginning in the second half of May 2020 and by the end of June 2020, the run rate of weekly OMIDRIA sales approximated levels seen prior to the pandemic.

Total costs and expenses for the first quarter of 2020 were $41.2 million compared to $36.1 million for the same period in 2019. The increase reflects incremental narsoplimab manufacturing costs together with increased costs supporting the preparation of our rolling BLA for HSCT-TMA in the U.S. Selling, general and administrative expenses were $16.9 million for both the second quarter of 2020 and the corresponding period in 2019.

For the three months ended June 30, 2020, Omeros reported a net loss of $33.3 million, or $0.61 per share, compared to a net loss of $14.5 million, or $0.29 per share, for the same period in 2019. Net loss in the second quarter of 2020 included non-cash expenses of $6.9 million, or $0.13 per share, while net loss in the second quarter of 2019 included non-cash expenses of $6.3 million, or $0.13 per share.

As of June 30, 2020, Omeros had $16.1 million of cash, cash equivalents and short-term investments available for operations and accounts receivable of $15.8 million.

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 inflammation, 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 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 August 10, 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.

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,	
	2020	2019	2020	2019
Revenue:				
Product sales, net	$ 13,530	$ 26,753	$ 37,067	$ 48,532
Costs and expenses:				
Cost of product sales	147	55	414	186
Research and development	24,132	19,108	53,043	45,363
Selling, general and administrative	16,931	16,928	34,967	31,560
Total costs and expenses	41,210	36,091	88,424	77,109
Loss from operations	(27,680)	(9,338)	(51,357)	(28,577)
Interest expense	(5,978)	(5,530)	(11,880)	(11,130)
Other income	364	415	912	909
Net loss	$ (33,294)	$ (14,453)	$ (62,325)	$ (38,798)
Comprehensive loss	$ (33,294)	$ (14,453)	$ (62,325)	$ (38,798)
Basic and diluted net loss per share	$ (0.61)	$ (0.29)	$ (1.14)	$ (0.79)
Weighted-average shares used to compute basic and diluted net loss per share	54,513,337	49,084,093	54,406,575	49,048,432

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	June 30, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 16,088	$ 60,788
Working capital	880	48,286
Restricted investments	1,154	1,154
Total assets	70,689	136,969
Total current liabilities	38,047	55,459
Lease liabilities	34,242	35,822
Unsecured convertible senior notes and lease financing obligations, net	163,372	158,213
Accumulated deficit	(796,936)	(734,611)
Total shareholders' deficit	(161,270)	(109,021)