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 8, 2019

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 8, 2019, Omeros Corporation issued a press release announcing financial results for the three and six months ended June 30, 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 August 8, 2019, pertaining to Omeros Corporation's financial results for the three and six months ended June 30, 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: August 8, 2019

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 2019 Financial Results

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

SEATTLE, WA – August 8, 2019 – 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, 2019.

Second Quarter 2019 Financial Highlights

- OMIDRIA® revenues for 2Q 2019 were a record high at $26.8 million. This compares to $21.8 million in 1Q 2019. The increase of $5.0 million, or 23 percent, over the prior quarter reflects both an expanded number of purchasing accounts and deeper penetration across Ambulatory Surgery Centers (ASCs), hospitals and the Veterans Administration and other government systems.
- Net loss in 2Q 2019 was $14.5 million, or $0.29 per share, which included non-cash expenses of $6.3 million, or $0.13 per share. This compares to a net loss $24.3 million, or $0.50 per share, in 1Q 2019.
- At June 30, 2019, Omeros had cash, cash equivalents and short-term investments available for operations of $31.8 million and an accounts receivable balance of $28.5 million.
- In August 2019, the company entered into a $50-million revolving line of credit facility with Silicon Valley Bank. Borrowing availability is based on eligible accounts receivable, subject to applicable reserves.

Recent Business Highlights

- Reached agreement with FDA on the primary endpoint criteria for the pivotal trial to support the biologics license application (BLA) for narsoplimab to treat hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA).
- As part of a successful pre-BLA meeting directed to chemistry, manufacturing and controls (CMC), the company discussed with FDA the CMC requirements for the narsoplimab BLA for HSCT-TMA and is confident in its ability to meet them.
- Executed a long-term commercial manufacturing agreement with Lonza in preparation for market launch of narsoplimab.
- Received a product-specific permanent J-code for OMIDRIA. The J-code will become effective October 1, 2019.

“OMIDRIA revenues continue to set new quarterly records as our customer base continues to broaden throughout all channels and our per-account capture of cataract procedures grows,” said Gregory A. Demopulos, M.D., Omeros’ chairman and chief executive officer. “Indications are that sales will continue to grow, helped in part by our new permanent J-code, broadening Med Advantage and commercial payer reimbursement, and additional strong clinical data that we believe places OMIDRIA squarely within CMS’ criteria for separate payment. As OMIDRIA ramps toward fully funding our pipeline, our assets increasingly declare their value – narsoplimab is moving toward anticipated approval and launch, OMS527 for addiction has successfully completed the Phase 1 clinical trial, OMS906 targeting the alternative complement pathway and our follow-on MASP-2 inhibitors are slated to enter the clinic beginning next year, and GPR174 inhibition appears to play a key role in cancer immunotherapy. Each of these unique and cutting-edge programs is focused on significantly improving – or saving – patients’ lives.”

Other Business Updates and Developments

- Recent developments regarding OMIDRIA include the following:
  - In July, CMS awarded a product-specific permanent J-code for OMIDRIA, which will become effective October 1, 2019. J-codes standardize the submission and payment of insurance claims across Medicare, Medicare Advantage, Medicaid and commercial insurance plans. The J-code should allow many commercial and Medicare Advantage insurers that currently do not reimburse under the existing C-code for OMIDRIA to reimburse under the permanent J-code. Omeros' commercial team has already initiated efforts to ensure that customers and payers are prepared to implement the new J-code.
  - Two independent studies in a total of approximately 2,800 cataract surgery patients demonstrate that OMIDRIA, compared to steroids, significantly reduces the incidence of cystoid macular edema (CME) by three to twelve-fold and breakthrough iritis as well as pain/photophobia, each by approximately three-fold. The studies are expected to be submitted later this month for peer-reviewed journal publication.
  - An independent investigator study shows that OMIDRIA, with statistical significance, reduces cataract surgery patients' requirement for perioperative opioids by nearly 80 percent while reducing visual analog scale (VAS) pain scores by more than 50 percent. The study results have been selected for presentation at the meetings of the American Academy of Ophthalmology in October and a manuscript is expected to be submitted later this month for publication in a peer-reviewed journal.
- 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:
  - All criteria for the response-based primary endpoint in Omeros' pivotal trial to support the BLA for narsoplimab to treat HSCT-TMA have now been finalized following agreement with FDA. The endpoint criteria are comprised of (1) laboratory markers reflecting disease progression and (2) organ function as a measure of clinical response. No additional patients are necessary for submission of the BLA. The majority of the data that comprise the BLA's clinical module are in-house and collection of the remaining data is underway. As part of a successful pre-BLA CMC meeting the company reached agreement with FDA on the narsoplimab BLA for HSCT-TMA with respect to chemistry, manufacturing and controls. Omeros has submitted to FDA its proposed schedule for a rolling BLA and is targeting submission of the BLA's first module by mid-next quarter.
  - Omeros and Lonza, a premier global drug manufacturer, executed a long-term commercial manufacturing agreement. Omeros and Lonza have partnered since 2015 in connection with the development of narsoplimab. The new multi-year agreement secures commercial supply of narsoplimab for use following anticipated regulatory approvals.
  - Omeros began meetings with the rapporteurs assigned by the European Medicines Agency to work with the company throughout the preparation and submission of the Marketing Authorization Application for narsoplimab in HSCT-TMA. Omeros plans to use the same clinical, manufacturing, and nonclinical data for approval in Europe.
  - In response to increasing physician demand, Omeros has expanded its compassionate use program for narsoplimab in HSCT-TMA. This expanded program provides patients and physicians with increased access to narsoplimab and will generate additional data useful in the drug's planned market launch.
  - Omeros' Phase 3 trial evaluating narsoplimab for IgA nephropathy, referred to as ARTEMIS-IGAN, continues enrollment at sites in the U.S., Europe and Asia. A manuscript detailing the clinical data from the Phase 2 IgA nephropathy program has been prepared by Omeros' Academic Leadership Committee and is being finalized for submission to a peer-reviewed journal.
  - A case report will soon be submitted for publication detailing the impressive response to narsoplimab treatment by a patient who was quickly deteriorating due to IgA vasculitis-associated nephritis and rapidly progressive glomerulonephritis.

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

  - Omeros' antibody against MASP-3, OMS906, continues to progress toward planned clinical entry in the first half of next year. Targeting subcutaneous dosing of once-monthly or longer, the initial focus in this program is paroxysmal nocturnal hemoglobinuria.
  - As part of lifecycle planning for its MASP-2 program, Omeros is advancing development of a long-acting second-generation MASP-2 antibody targeting monthly subcutaneous delivery as well as an orally available small-molecule inhibitor of MASP-2. Both programs are slated for clinical entry by mid-2021.
  - Dosing is complete in the Phase 1 trial for OMS527, the lead compound in Omeros' phosphodiesterase 7 (PDE7) program, which targets treatment of addiction and compulsive disorders. The compound was generally well tolerated with no significant adverse events being reported. The pharmacokinetic data support once-daily dosing, with or without food. Data analysis is being finalized, and detailed study results will soon be released. Omeros plans to conduct a Phase 2a study targeting nicotine addiction.

Financial Results

2Q 2019 revenues were a record-high $26.8 million, all relating to sales of OMIDRIA. On a sequential quarter-over-quarter basis, OMIDRIA revenues increased by $5.0 million, or 23 percent, from the $21.8 million achieved in 1Q 2019. The increase is due to a growing number of ASCs and hospitals using OMIDRIA for cataract surgery as well as deeper penetration within individual accounts.

Inventory on hand at wholesalers at June 30, 2019 remained consistent with historical norms. Gross-to-net deductions increased slightly from 27 percent in 1Q 2019 to 28 percent in 2Q 2019, primarily due to increased chargebacks and rebates.

Total 2Q 2019 costs and expenses were $36.1 million compared to $41.0 million for 1Q 2019. The decrease reflected reduced narsoplimab manufacturing costs, which vary from quarter to quarter depending on the timing of manufacturing development activities, partially offset by an increase in selling, general and administrative expense.

For 2Q 2019, Omeros reported a net loss of $14.5 million, or $0.29 per share, which included non-cash expenses of $6.3 million ($0.13 per share). In comparison, for 1Q 2019 Omeros reported a net loss of $24.3 million, or $0.50 per share, which included non-cash expenses of $6.0 million ($0.12 per share).

As of June 30, 2019, the company had $31.8 million of cash, cash equivalents and short-term investments available for operations. In August 2019, the company entered into a loan and security agreement under which Omeros may borrow, on a revolving basis, up to $50 million, subject to applicable reserves and an available borrowing base of eligible accounts receivable.

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 1697797. 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 1697797.

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 as well as orphan indications targeting inflammation, complement-mediated diseases, disorders of the central nervous system and immune-related diseases, including cancers. The company's drug product OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is marketed for use during cataract surgery or intraocular lens (IOL) replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. In the European Union, the European Commission has

approved OMIDRIA for use in cataract surgery and other IOL replacement procedures to maintain mydriasis (pupil dilation), prevent miosis, and to reduce postoperative eye pain.

Omeros has multiple Phase 3 and Phase 2 clinical-stage development programs focused on complement-associated thrombotic microangiopathies, complement-mediated glomerulonephropathies, cognitive impairment and addictive and compulsive disorders. In addition, Omeros has a diverse group of preclinical programs and a proprietary G protein-coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and corresponding compounds, a number of which are in preclinical development. 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, 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 1, 2019, as supplemented from time to time by the company's Quarterly Reports on Form 10-Q. 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:
Jennifer Cook Williams
Cook Williams Communications, Inc.
Investor and Media Relations
360.668.3701
jennifer@cwcomm.org

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,	
	2019	2018	2019	2018
Revenue:				
Product sales, net	$ 26,753	$ 1,655	$ 48,532	$ 3,244
Costs and expenses:				
Cost of product sales	55	116	186	319
Research and development	19,108	19,412	45,363	37,551
Selling, general and administrative	16,928	12,744	31,560	23,678
Total costs and expenses	36,091	32,272	77,109	61,548
Loss from operations	(9,338)	(30,617)	(28,577)	(58,304)
Interest expense	(5,530)	(3,676)	(11,130)	(6,502)
Other income	415	597	909	1,056
Net loss	$ (14,453)	$ (33,696)	$ (38,798)	$ (63,750)
Comprehensive loss	$ (14,453)	$ (33,696)	$ (38,798)	$ (63,750)
Basic and diluted net loss per share	$ (0.29)	$ (0.70)	$ (0.79)	$ (1.32)
Weighted-average shares used to compute basic and diluted net loss per share	49,084,093	48,384,460	49,048,432	48,333,610

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	June 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 31,845	$ 60,498
Working capital	25,271	52,511
Restricted investments	1,154	1,154
Total assets	89,760	95,936
Total current liabilities	40,673	37,356
Lease liabilities	28,581	2,467
Convertible Senior Notes	153,416	148,981
Accumulated deficit	(688,923)	(650,125)
Total shareholders' deficit	(130,274)	(100,156)