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): November 9, 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 November 9, 2021, Omeros Corporation issued a press release announcing financial results for the three and nine months ended September 30, 2021. 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 November 9, 2021, pertaining to Omeros Corporation's financial results for the three and nine months ended September 30, 2021.
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: November 9, 2021

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

Omeros Corporation Reports Third Quarter 2021 Financial Results

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

SEATTLE, WA – November 9, 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, immunologic diseases (e.g., complement-mediated diseases and cancers) and central nervous system disorders, today announced recent highlights and developments as well as financial results for the third quarter ended September 30, 2021, which include:

- OMIDRIA revenues for the third quarter of 2021 were $30.0 million compared to $28.8 million in the second quarter. The 4.1 percent increase over the prior quarter primarily reflects growth in sales of OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% in ambulatory surgery centers (ASCs).

- Net loss in the third quarter of 2021 was $22.7 million, or $0.36 per share, including non-cash expenses of $6.4 million, or $0.10 per share. This compares to a net loss of $28.6 million, or $0.46 per share, which included non-cash expenses of $3.9 million, or $0.06 per share, for the previous quarter.

- At September 30, 2021, Omeros had cash, cash equivalents and short-term investments available for operations of $50.4 million.

- In early November, the Centers for Medicare and Medicaid Services (CMS) reconfirmed that OMIDRIA qualifies for separate payment in the ASC setting under CMS' policy regarding non-opioid pain management surgical drugs.

- On October 18, 2021, Omeros announced the receipt of a Complete Response Letter from the U.S. FDA regarding the Company's biologics license application (BLA) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). Omeros is preparing for a Type A meeting with FDA to determine the most expeditious path forward for approval of narsoplimab in the treatment of HSCT-TMA.

"With CMS reconfirming separate payment for OMIDRIA in the ASC setting, Omeros, together with cataract surgeons and facility administrators, is appreciative and confident that patients will continue to be able to access OMIDRIA, improving surgical outcomes," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "This is reflected in continued sales growth, with an increasing percentage of Medicare Advantage and commercial payers also recognizing the benefits of the drug and appropriately reimbursing for its use. The increasing OMIDRIA revenues are important as we focus our resources on our complement programs, primarily to achieve FDA approval of the narsoplimab BLA in HSCT-TMA and to drive the other high-priority components of our complement franchise – the Phase 3 trial of narsoplimab in IgA nephropathy and our MASP-3 inhibitor OMS906, which we plan to accelerate from a Phase 1 trial in healthy subjects to assessing the drug in PNH patients. We expect that our portfolio of commercial and development programs will continue to advance throughout 2022, and we look forward to capitalizing on the opportunities that the coming year holds."

Third Quarter and Recent Developments

- Recent developments regarding OMIDRIA include the following:

- In early November, CMS released its Outpatient Prospective Payment System (OPPS) and ASC Payment System final rule for calendar year 2022. The final rule reconfirms that OMIDRIA qualifies for separate payment in the ASC setting under CMS' policy regarding non-opioid pain management surgical drugs.

- The NOPAIN Act continues to attract strong bipartisan support in both chambers of Congress, with 34 sponsors in the Senate and 74 in the House of Representatives. If enacted, the bill would mandate, for a renewable period of 5 years, Medicare separate payment in both the ASC and hospital outpatient settings for non-opioid surgical pain management drugs, like OMIDRIA, that have demonstrated in a clinical trial or through data published in a peer-reviewed journal the ability to replace or avoid opioid use or reduce the quantity of opioids prescribed.

- A manuscript reporting the results of an independent investigator study demonstrating that the administration of OMIDRIA during cataract surgery is associated with reduced use of intraoperative fentanyl and concurrent pain reduction was published online in the *Journal of Cataract and Refractive Surgery*. The results of the study are consistent with those of an earlier study published in *Clinical Ophthalmology*.

- A review article discussing the evolution of pain management in cataract surgery, particularly the use and associated risks of opioids in cataract surgery and how the use of non-opioid alternatives, with a focus on OMIDRIA, can help to address the opioid crisis was also accepted for publication in the *Journal of Cataract and Refractive Surgery*.

- Recent developments regarding narsoplimab, Omeros' lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2) in advanced clinical programs for the treatment of HSCT-TMA, immunoglobulin A (IgA) nephropathy, atypical hemolytic uremic syndrome (aHUS) and severely ill COVID-19 patients, include the following:

  - Results from long-term follow-up from the completed Phase 2 clinical trial evaluating narsoplimab in patients with IgA nephropathy were presented by Dr. Richard Lafayette, Professor of Medicine and Director of the Glomerular Disease Center at Stanford University, at the annual congress of the American Society of Nephrology (ASN). Adults with severe IgA nephropathy receiving narsoplimab treatment were followed for up to 35 months and showed that narsoplimab treatment resulted in sustained proteinuria reduction and a markedly slowed rate of decline of estimated glomerular filtration rate (eGFR). Patients received a median of one 12-week course of narsoplimab annually, with 58 percent of patients receiving only one course per year or less. Overall, patients' renal function, as assessed by eGFR, improved (25 percent of patients) or stabilized versus an external control group matched for proteinuria and eGFR.

    Using the same analytical approach adopted by other companies* to determine the impact of proteinuria reduction on long-term risk of need for dialysis, the unprecedented 64.4 percent reduction in proteinuria that was seen in the Phase 2 narsoplimab-treated patients is predicted to delay progression to renal dialysis by more than 41.6 years compared to standard of care, a substantially longer projected delay to need for dialysis than has been reported for any other drug in development for the treatment of renal disease.

  - Another presentation at ASN was the first report of the effects of lectin-pathway inhibition on urinary complement levels in kidney disease. The presentation assessed complement levels in urinary samples collected during the clinical course of a rapidly deteriorating young woman with IgA vasculitis. Narsoplimab treatment was associated with substantial reduction in markers of local complement activation and stabilization of kidney function as measured by eGFR. The work was conducted by a consortium led by Peter Garred, MD, DMSc, Chair and Professor of Clinical Molecular Medicine at the University of Copenhagen.

- Last month a manuscript examining the significance of the lectin pathway of complement in the pathogenesis of IgA nephropathy and the role of lectin pathway inhibition with narsoplimab as a potential therapeutic approach was published in the *Journal of Clinical Medicine*. Dr. Mohamed Daha, Professor Emeritus in the Department of Nephrology at Leiden University, is the paper's senior author.
- Two manuscripts are being prepared for publication based on work conducted at Omeros' collaborative laboratories at the University of Cambridge. The first is directed to a profile of disease-specific complement-marker abnormalities identified by our team studying hospitalized COVID-19 patients in the two major hospitals affiliated with the University of Cambridge and a large number of sera from the U.K.'s national COVID-response biobank. The data demonstrate that, very early in severe COVID-19, lectin pathway hyperactivation occurs and causes consumption of the complement components shared between the lectin and classical pathways, impairing classical pathway function. Narsoplimab, by blocking lectin pathway activation, has now been shown to restore classical pathway function in COVID-19 patients. Omeros is developing a broad intellectual property position directed to a profile of complement biomarkers – and their associated assays – as a potentially early indicator of severe COVID-19 and as means to assess therapeutic response.

  The second manuscript further examines the finding that lectin pathway hyperactivation severely impairs the classical complement activation pathway, which critically supports the infection-fighting adaptive immune response. A substantial incidence of life-threatening secondary infections occur in severe COVID-19. The data suggest that, by blocking the lectin pathway, narsoplimab could allow recovery of classical pathway functional activity and protect against infection by maintaining the complement-dependent antimicrobial defense of adaptive immunity in severe COVID-19 patients.

- Updates regarding Omeros' other development programs and platforms include the following:
  - Recent data from our Phase 1 clinical trial evaluating the safety, tolerability, pharmacodynamics and pharmacokinetics of our lead MASP-3 inhibitor antibody, OMS906, show high level suppression of alternative complement pathway activity. We have decided to forego the multiple-ascending dose portion of our Phase 1 trial in healthy subjects in favor of moving directly into patients with paroxysmal nocturnal hematuria, or PNH, who have an unsatisfactory response to the C5 inhibitor ravulizumab. We expect this shift to accelerate our overall clinical program evaluating OMS906 in PNH.

Financial Results

For the third quarter of 2021, OMIDRIA revenues were $30.0 million compared to $28.8 million for the second quarter, an increase of $1.2 million or 4.1 percent.

Total costs and expenses for the third quarter of 2021 were $48.3 million compared to $52.8 million for the preceding quarter. The decrease in the third quarter was primarily due to reduced preclinical research and development costs.

For the three months ended September 30, 2021, Omeros reported a net loss of $22.7 million, or $0.36 per share, which included non-cash expenses of $6.4 million, or $0.10 per share. This compares to a net loss in the previous quarter of $28.6 million, or $0.46 per share, which included non-cash expenses of $3.9 million, or $0.06 per share.

As of September 30, 2021, the company had $50.4 million of cash, cash equivalents and short-term investments. The company also has a line of credit, which permits borrowing up to the lesser of $50 million or 85 percent of eligible accounts receivable, less certain reserves. Omeros also has an "at the market" program in place that allows the company to sell, from time to time, up to $150 million of its common stock.

Conference Call Details

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 7744465. 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 7744465.

To access the live or subsequently archived webcast of the conference call on the internet, go to the company's website at

https://investor.omeros.com/upcoming-events.

---

[*]Carroll K. et al., Estimating Delay in Time to ESKD for Treatment Effects on Proteinuria in IgA Nephropathy and FSGS. ERA-EDTA 2021, Oral Presentation; and Calliditas Therapeutics AB, April 2019, Investor Day Webinar.

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, immunologic diseases (e.g., complement-mediated diseases and cancers) and central nervous system disorders. 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 pending before 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. Omeros' immune-oncology portfolio also includes a novel cell therapy platform designed to markedly improve response rates for patients receiving CAR-T or adoptive tumor-infiltrating T-cell therapies for liquid or solid tumors. 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, including expectations with regard to interactions and communications with FDA and Omeros' pursuit of regulatory approval for narsoplimab in HSCT-TMA, 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, challenges associated with manufacture or supply of our investigational or commercial products, 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.

Contact:

Jennifer Cook Williams
Cook Williams Communications, Inc.
Investor and Media Relations
IR@omeros.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product sales, net	$ 30,004	$ 26,114	$ 79,889	$ 63,181
Costs and expenses:				
Cost of product sales	333	401	938	815
Research and development	27,063	31,316	91,358	84,359
Selling, general and administrative	20,861	19,825	60,474	54,792
Total costs and expenses	48,257	51,542	152,770	139,966
Loss from operations	(18,253)	(25,428)	(72,881)	(76,785)
Loss on early extinguishment of debt	—	(13,374)	—	(13,374)
Interest expense	(4,911)	(6,882)	(14,719)	(18,763)
Other income	461	(633)	1,214	280
Loss before income tax benefit	(22,703)	(46,317)	(86,386)	(108,642)
Income tax benefit	—	7,854	—	7,854
Net loss	$ (22,703)	$ (38,463)	$ (86,386)	$ (100,788)
Comprehensive loss	$ (22,703)	$ (38,463)	$ (86,386)	$ (100,788)
Basic and diluted net loss per share	$ (0.36)	$ (0.66)	$ (1.39)	$ (1.81)
Weighted-average shares used to compute basic and diluted net loss per share	62,510,727	58,233,988	62,267,557	55,682,379

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 50,372	$ 134,953
Working capital	48,531	114,549
Restricted investments	1,054	1,055
Total assets	123,430	181,042
Total current liabilities	42,818	36,736
Lease liabilities	35,383	32,552
Unsecured convertible senior notes, net	313,018	236,288
Accumulated deficit	(963,755)	(872,672)
Total shareholders' deficit	(262,697)	(120,752)