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, 2022

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, 2022, Omeros Corporation issued a press release announcing financial results for the three and nine months ended September 30, 2022. 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, 2022, pertaining to Omeros Corporation's financial results for the three and nine months ended September 30, 2022.
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, 2022

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

Exhibit 99.1

Omeros Corporation Reports Third Quarter 2022 Financial Results

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

SEATTLE, WA – November 9, 2022 – Omeros Corporation (Nasdaq: OMER), a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation and immunologic diseases, including complement-mediated diseases and cancers, today announced recent highlights and developments as well as financial results for the third quarter ended September 30, 2022, which include:

- For the quarter ended September 30, 2022, we earned royalties of $16.5 million on net sales of our former ophthalmology product OMIDRIA®. Royalties earned in the quarter represent 50 percent of net sales of OMIDRIA by Rayner Surgical, Inc. (Rayner), which purchased our ophthalmology assets in December 2021. Rayner's U.S. net sales of OMIDRIA were $33.0 million for the third quarter of 2022.

- Net loss in 3Q 2022 was $17.5 million, or $0.28 per share, which included $4.6 million of non-cash expenses, or $0.07 per share. This compares to a net loss of $22.7 million, or $0.36 per share for the prior year quarter, which included $6.4 million of non-cash expenses, or $0.10 per share.

- On September 30, 2022, we sold to DRI Healthcare Acquisitions LP (DRI) an interest in a portion of our future OMIDRIA royalty receivables for a cash purchase price of $125.0 million. The purchased royalty interest entitles DRI to receive royalty payments on OMIDRIA net sales between September 1, 2022 and December 31, 2030, up to the amount of maximum caps established for each annual period. The maximum aggregate payout DRI is entitled to receive is $188.4 million.

- At September 30, 2022, we had $221.0 million of cash, cash equivalents and short-term investments.

- As announced yesterday, we received the decision by FDA's Office of New Drugs (OND) denying our appeal of the complete response letter (CRL) issued earlier by FDA concerning the biologics license application (BLA) for narsoplimab in hematopoietic stem cell transplant-associated microangiopathy (TA-TMA). Although our request for immediate resubmission and labeling discussions was denied, the decision proposes a path forward for resubmission of the BLA based on survival data from the completed pivotal trial versus a historical control group, with or without an independent literature analysis.

- In November 2022, the Centers for Medicare and Medicaid Services (CMS) issued its final Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems rule for calendar year 2023. The rule confirms that for calendar year 2023 CMS will continue to pay separately for OMIDRIA when used in ambulatory surgical centers.

"FDA's decision on our CRL appeal request provides paths forward that are based on a comparison of patient survival in our pivotal trial to historical survival data in TA-TMA and to response data in the literature. Together with our regulatory and legal advisors, we are assessing potential next steps and look forward to working with the Agency to approve narsoplimab as quickly as possible," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "Also heading into 2023, we have established financial flexibility with our royalty monetization transaction, which could be further strengthened by our receipt of the $200-million OMIDRIA-related milestone payment. From our clinical trials, throughout the coming year we anticipate data from our MASP-3 inhibitor OMS906 in PNH and C3 glomerulopathy beginning in the first quarter, from our Phase 1 program for our long-acting MASP-2 inhibitor in the second quarter and,

in mid-year, from our narsoplimab Phase 3 trial in IgA nephropathy. We also expect news from our OMS527 PDE7 inhibitor and immuno-oncology programs. All of these assets are rapidly advancing – collectively representing significant opportunities and substantial enterprise value."

Third Quarter and Recent Clinical Developments

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

    - On October 18, 2021, we announced the receipt of a CRL from FDA indicating that the BLA for narsoplimab in TA-TMA could not be approved as submitted. Following additional interactions with FDA regarding the BLA we submitted a Formal Dispute Resolution Request, in June 2022, appealing the issuance of the CRL to a higher level within FDA, in this case OND, and requesting that OND direct the review division to accept a Class 1 resubmission of the BLA and to commence labeling discussions immediately thereafter. In November 2022, we received OND's decision denying our appeal. Although our request for immediate resubmission and labeling discussions was denied, the decision proposes a path forward for the resubmission of the BLA based on survival data from the completed pivotal trial versus a historical control group. Specifically, the decision proposes the resubmission of the narsoplimab BLA including a comparison of the existing response data from the completed pivotal trial to a threshold derived from an independent literature analysis and evidence of increased survival from patients in the pivotal trial compared to an appropriate historical control group. It also notes that persuasive evidence of superior survival versus a well-matched historical control group could be sufficient even in the absence of the independent literature analysis. The specific approach to any resubmission and its details would be determined through discussion with the review division.

    - Enrollment in our Phase 3 ARTEMIS-IGAN trial continues to progress toward an anticipated readout of 9-month data on proteinuria by mid-next year.

    - A case report describing the successful treatment of an adult patient with recurrent IgA nephropathy under compassionate use was presented at the American Society of Nephrology's kidney week congress held last week in Orlando, Florida. The poster presentation is entitled *Narsoplimab Treatment for Recurrent IgA Nephropathy Stabilized eGFR and Proteinuria.*

    - A poster presentation describing the design of our open-label Phase 2 study evaluating efficacy and safety of narsoplimab in pediatric patients with high-risk TA-TMA will be presented at the annual meeting of the American Society of Hematology to be held in December 2022 in New Orleans, Louisiana.

    - In September 2022, results of the narsoplimab treatment arm of the I-SPY COVID-19 adaptive platform trial sponsored by Quantum Leap Healthcare Collaborative were announced. Although the narsoplimab treatment arm was terminated prior to accrual of the maximum of 125 patients, analysis in the randomized patient population showed that the addition of narsoplimab to treatment of critically ill patients with COVID-19 reduces the mortality risk (hazard ratio [HR]=0.81, with probability [HR <1] equal to 0.77). In approximately half of the patients who died in the narsoplimab group, narsoplimab was not given or was prematurely stopped, with those patients dying 9 to 35 days later. Neither the trial's futility nor graduation criteria had been met in the analysis of the randomized population at the time the narsoplimab arm was terminated; however, Quantum Leap's data monitoring committee terminated the narsoplimab treatment arm on the basis of analysis in a population of pre-consented patients in which substantial imbalance was detected, resulting in a marked bias against the narsoplimab arm.

- Recent developments regarding OMS906, our lead monoclonal antibody targeting MASP-3, the key activator of the alternative pathway, and OMS1029, the company's long-acting, next-generation MASP-2 inhibitor, include the following:

- We expect soon to begin enrolling patients in a Phase 1b clinical trial evaluating OMS906 in patients with paroxysmal nocturnal hemoglobinuria (PNH) who have had an unsatisfactory response to the C5 inhibitor ravulizumab. Regulatory submissions and site selection are also progressing on a planned expansion of clinical programs designed to evaluate OMS906 in treatment-naïve PNH patients, patients with complement 3 (C3) glomerulopathy and, potentially, patients with one or more related indications. Initial efficacy data from these open-label studies are targeted for availability in early 2023.

- A poster presentation describing the results of a Phase 1 single-ascending-dose clinical trial of OMS906 in normal human volunteers will be featured at the annual meeting of the American Society of Hematology to be held in December 2022 in New Orleans, Louisiana.

- A Phase 1 clinical trial assessing safety, tolerability and pharmacokinetics/pharmacodynamics (PK/PD) of OMS1029 in healthy subjects is underway, with dosing of the first three of six cohorts in the single-ascending-dose study now complete. Dosing of OMS1029 is expected to be once-monthly to once-quarterly by subcutaneous or intravenous administration. This next-generation MASP-2 inhibitor is intended as complementary to narsoplimab, enabling us to pursue both acute and chronic indications and to provide a significant benefit of dosing convenience to patients.

Financial Results

On September 30, 2022, we sold to DRI an interest in a portion of our future OMIDRIA royalty receivables in exchange for $125.0 million in cash consideration. DRI is entitled to receive royalties on OMIDRIA net sales between September 1, 2022 and December 31, 2030, up to the amount of a fixed annual cap. DRI receives payment of royalties monthly, as received from Rayner, up to the amount of a prorated monthly cap amount before we receive any royalty proceeds. DRI is not entitled to carry-forward nor recoup any shortfall if the royalties paid by Rayner for an annual period are less than the cap amount for the applicable calendar year. Additionally, DRI has no recourse to or security interest in our assets other than our OMIDRIA royalty receivables. We retain all royalty receipts in excess of the respective cap in any given year. The maximum aggregate payout DRI is entitled to receive is $188.4 million which, if fully paid, is an effective interest rate of 9.4%. The maximum amount payable for the remainder of 2022 is $1.7 million. The maximum amount payable in 2023 is $13.0 million. Assuming the maximum amount is paid each year, DRI will recoup the $125 million purchase price in August 2028.

During the third quarter of 2022, we earned royalties of $16.5 million on sales of OMIDRIA, which were recorded as a reduction from the OMIDRIA contract royalty asset. We also recorded $37.3 million of income in discontinued operations, primarily representing interest income and remeasurement adjustments to the OMIDRIA contract royalty asset.

Total costs and expenses for the third quarter of 2022 were $50.8 million compared to $39.8 million for the third quarter of 2021. The increase was primarily due to the manufacturing of narsoplimab drug substance in the third quarter of 2022 for future commercial and clinical use.

Net loss was $17.5 million in the third quarter of 2022, or $0.28 per share, which included $4.6 million of non-cash expenses, or $0.07 per share. This compares to a net loss of $22.7 million, or $0.36 per share, including $6.4 million of non-cash expenses, or $0.10 per share, in 3Q 2021.

As of September 30, 2022, we had $221.0 million of cash, cash equivalents and short-term investments.

Conference Call Details

To access the live conference call via phone, participants must register at the following link to receive a unique PIN: https://register.vevent.com/register/BI4363ad5bbf154eef81c3be16f4e47738. Once registered, you will have two options: (1) Dial in to the conference line provided at the registration site using the PIN provided to you, or (2) choose the “Call Me” option, which will instantly dial the phone number you provide. Should you lose your PIN or registration confirmation email, simply re-register to receive a new PIN.

For online access to the live or subsequently archived webcast of the conference call, go to Omeros' website at https://investor.omeros.com/upcoming-events.

About Omeros Corporation

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders including complement-mediated diseases, cancers, and addictive and compulsive disorders. 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 (TA-TMA). Narsoplimab is also in multiple late-stage clinical development programs focused on other complement-mediated disorders, including IgA nephropathy, COVID-19, and atypical hemolytic uremic syndrome. Omeros' long-acting MASP-2 inhibitor OMS1029 is currently in a Phase 1 clinical trial. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is advancing in clinical programs for paroxysmal nocturnal hemoglobinuria (PNH), complement 3 (C3) glomerulopathy and one or more related indications. 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 statements regarding prospects for obtaining FDA approval of narsoplimab in TA-TMA and potential next steps in relation to the biologics license application for narsoplimab following the receipt of FDA's decision on Omeros' formal dispute resolution request, expectations regarding the initiation or continuation of clinical trials evaluating Omeros' drug candidates and the anticipated availability of data therefrom, and expectations regarding growth in royalty-generating sales, 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, unanticipated or unexpected outcomes of regulatory processes in relevant jurisdictions, unproven preclinical and clinical development activities, financial condition and results of operations, regulatory processes and oversight, challenges associated with manufacture or supply of our investigational or clinical 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 on March 1, 2022. 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:

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OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Costs and expenses:				
Research and development	$ 38,568	$ 25,818	$ 86,172	$ 88,448
Selling, general and administrative	12,198	14,010	37,079	42,280
Total costs and expenses	50,766	39,828	123,251	130,728
Loss from continuing operations	(50,766)	(39,828)	(123,251)	(130,728)
Interest expense	(4,932)	(4,911)	(14,799)	(14,718)
Interest and other income	906	461	2,069	1,212
Net loss from continuing operations	(54,792)	(44,278)	(135,981)	(144,234)
Net income from discontinued operations (1)	37,336	21,575	54,665	57,848
Net loss	$ (17,456)	$ (22,703)	$ (81,316)	$ (86,386)
Basic and diluted net income (loss) per share:				
Net loss from continuing operations	$ (0.87)	$ (0.70)	$ (2.17)	$ (2.32)
Net income from discontinued operations (1)	0.59	0.34	0.87	0.93
Net loss	$ (0.28)	$ (0.36)	$ (1.30)	$ (1.39)
Weighted-average shares used to compute basic and diluted net income (loss) per share	62,730,015	62,510,727	62,728,276	62,267,557

(1) The sale of OMIDRIA has been accounted for as the sale of an asset. Accordingly, we have reclassified all revenues and expenses related to OMIDRIA to net income from discontinued operations for the three and nine months ended September 30, 2021 in our financial statements.

OMEROS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEET DATA
(In thousands)
(unaudited)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and short-term investments	$ 220,964	$ 157,266
OMIDRIA contract royalty asset	191,385	184,570
Total assets	457,551	419,268
Total current liabilities	39,514	51,789
Lease liabilities	27,942	34,381
Unsecured convertible senior notes, net	314,819	313,458
OMIDRIA royalty obligation	125,000	—
Total shareholders' equity (deficit)	(46,314)	23,780
Working capital	249,031	196,167

OMEROS CORPORATION
CONDENSED CONSOLIDATED SUPPLEMENTAL DATA
(In thousands)
(unaudited)

The following schedule presents a rollforward of the OMIDRIA contract royalty asset:

OMIDRIA contract royalty asset at December 31, 2021	$ 184,570
Royalties earned	(47,555)
Royalty interest income and other	23,857
Remeasurement adjustments	30,513
OMIDRIA contract royalty asset at September 30, 2022	$ 191,385

Net income from discontinued operations is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(In thousands)			
Product sales, net	$ —	$ 30,004	$ —	$ 79,888
Royalty interest income	8,229	—	23,857	—
Remeasurement adjustments	29,043	—	30,513	—
Other income (expenses), net	64	(8,429)	295	(22,040)
Net income from discontinued operations	$ 37,336	$ 21,575	$ 54,665	$ 57,848