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 13, 2024

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 13, 2024, Omeros Corporation issued a press release announcing financial results for the three and nine months ended September 30, 2024. 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, including any information contained on or accessible through any website reference in the 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. The inclusion of any website address in this Current Report on Form 8-K by incorporation by reference of the press release is as an inactive textual reference only.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release, dated November 13, 2024, pertaining to Omeros Corporation's financial results for the three months and nine months ended September 30, 2024.
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 13, 2024

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 2024 Financial Results

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

SEATTLE, WA – November 13, 2024 – Omeros Corporation (Nasdaq: OMER) today announced recent highlights and developments as well as financial results for the third quarter ended September 30, 2024, which include:

- Net loss for the third quarter of 2024 was $32.2 million, or $0.56 per share, compared to a net loss of $37.8 million, or $0.60 per share for the third quarter of 2023. For the nine months ended September 30, 2024, net loss was $125.5 million, or $2.15 per share, compared to a net loss of $108.8 million, or $1.73 per share in the prior year period.

- At September 30, 2024, we had $123.2 million of cash and short-term investments available for operations and debt servicing, a decrease of $48.7 million from December 31, 2023. During the year, we paid an $18.4 million charge related to delivery of narsoplimab drug substance, the manufacturing of which commenced in October 2023, a $21.2 million payment for term loan-related debt repurchase, and $1.9 million of term loan-related transaction costs.

- In September, we held a presubmission meeting with FDA for our biologics license application ("BLA") for narsoplimab, our lead antibody targeting MASP-2 and the lectin pathway of complement, in hematopoietic stem cell transplant-associated thrombotic microangiopathy ("TA-TMA"). The meeting was both collaborative and productive. As part of the meeting, we received additional minor feedback on our proposed statistical analysis plan for the primary endpoint – patient survival in our pivotal narsoplimab trial compared to that in an external registry of patients with TA-TMA. FDA had previously reviewed the plan and all comments had been incorporated. The additional feedback was limited to requesting a few additional sensitivity analyses. We accordingly revised and resubmitted our statistical analysis plan shortly thereafter and expect to receive FDA's reply imminently. Assuming general alignment on the revised plan, we intend to proceed with conducting the primary and secondary efficacy analyses after incorporating, as appropriate any additional agency feedback on the plan. If the results support resubmission, we intend to finalize and resubmit our BLA as soon as possible. We expect to provide a further update on our plans for resubmission and relevant timing after the efficacy analyses have been conducted.

- Preparations are also underway for the European marketing authorization application ("MAA") for narsoplimab in TA-TMA, which we expect to submit in the first half of 2025.

- Zaltenibart (formerly known as OMS906), our lead MASP-3 antibody targeting the key activator of the alternative pathway of complement, continued to advance rapidly through its Phase 2 development program in paroxysmal nocturnal hemoglobinuria ("PNH"). In September and October 2024, we met with FDA and European regulators to discuss further details of our planned Phase 3 program for zaltenibart in PNH. With both regulatory agencies, we discussed data developed from our clinical and nonclinical programs to date as well as our plans for Phase 3 development of zaltenibart in PNH. Both regulatory agencies agreed with the design of our proposed studies as well as our dose-finding strategy and provided other valuable feedback to inform our development plans. We now have a clear path to opening Phase 3 enrollment, which we expect in early 2025.

- Sites for the zaltenibart Phase 2 trial in C3 glomerulopathy ("C3G") are open to enrollment in multiple countries and dosing in the study is ongoing. We are targeting initiation of our Phase 3 program for C3G in the first half of 2025.

"We expect that our September presubmission meeting with FDA and the minor revisions requested and incorporated in our analysis plan should clear the way to resubmit our BLA for narsoplimab in TA-TMA," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "While driving toward BLA and MAA submissions and preparing for the market launch of narsoplimab, we have also made tremendous progress in our other clinical development programs. For zaltenibart – with strong and growing physician support – successful end-of-Phase-2 meetings with both FDA and European regulators together with the manufacturing of sufficient drug supply enable us to advance directly into Phase 3 PNH enrollment, planned for early 2025, with C3G Phase 3 initiation targeted to follow soon thereafter. As we identify an appropriate large-market indication, our long-acting MASP-2 inhibitor OMS1029 stands ready to begin Phase 2 clinical trials. In our OMS527 program targeting addictive and compulsive disorders, we anticipate starting next year our NIDA-funded trial in adult patients with cocaine-use disorder. In parallel, our preclinical oncology programs are rapidly generating exciting *in vitro* and *in vivo* data as we build our patent position. We look forward to sharing more about the progress and prospects of all these programs in the coming months."

Third Quarter and Recent Clinical Developments

- Recent developments regarding narsoplimab, our lead monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 ("MASP-2"), the effector enzyme of the lectin pathway, include the following:

    - We have been engaged in ongoing discussions with FDA regarding the anticipated resubmission of our BLA for narsoplimab in TA-TMA, as described above. We do not expect the need for any additional discussion following FDA's pending reply to our September submission of the revised statistical analysis plan incorporating requested additional sensitivity analyses so, following receipt of FDA's response, we intend to proceed with conducting the primary and secondary efficacy analyses after incorporating, as appropriate, any additional agency feedback on the plan. If the analysis results support resubmission, we intend to finalize and resubmit our BLA as soon as possible. Even if the results of the efficacy analysis are favorable and FDA accepts our resubmitted BLA for review, as with any BLA or new drug application ("NDA"), there can be no guarantee that FDA will approve narsoplimab for TA-TMA. We expect to provide a further update on our plans for resubmission and relevant timing after the efficacy analyses have been performed.

    - Preparations are also underway for the European MAA for narsoplimab in TA-TMA, which we expect to submit in the first half of 2025.

    - Two manuscripts are in preparation by panels of leading international transplant experts - the first will compare survival in patients in the narsoplimab pivotal trial to survival in the same rigorous external control population of TA-TMA patients to be used in our BLA primary analysis and the second detailing the survival data of nearly 140 adult and pediatric TA-TMA patients treated with narsoplimab under our expanded access program. Physicians continue to request access to narsoplimab under this program for their patients with TA-TMA, many who have failed off-label treatment with one or more other complement inhibitors and/or defibrotide.

    - We are continuing our work exploring the potential of narsoplimab and MASP-2 inhibition in severe acute and long COVID (also known as post-acute sequelae of COVID-19, or PASC) as well as acute respiratory distress syndrome, or ARDS, including ARDS associated with H1N1 and H5N1 infection. We are also advancing a MASP-2/C1inh proprietary diagnostic assay for lectin pathway hyperactivation for use in severe acute and long COVID-19, ARDS, and other diseases and disorders.

- Recent developments regarding OMS1029, our long-acting, next-generation MASP-2 inhibitor, include the following:

    - Single- and multiple-ascending-dose Phase 1 studies of OMS1029 have now been completed and OMS1029 has been well tolerated to date with no safety concerns identified. Results of these studies, confirmed by pharmacokinetic and pharmacodynamic modeling and dose simulation, confirm once-quarterly, low-volume dosing either intravenously or subcutaneously.

    - OMS1029 drug product has been manufactured and stored for future clinical trials and we continue to evaluate large-market indications in which to pursue Phase 2 clinical development of OMS1029, dependent on the availability of resources. Data from a primate study in one of these indications are pending.

- Recent developments regarding zaltenibart, our lead monoclonal antibody targeting mannan-binding lectin-associated serine protease-3 ("MASP-3"), the key activator of the alternative pathway, include the following:

    - Results from the zaltenibart monotherapy stage of our Phase 2 "switch-over" trial evaluating two doses of zaltenibart in PNH patients who have had an unsatisfactory response to the C5 inhibitor ravulizumab will be presented in December at the Annual Meeting of the American Society of Hematology ("ASH"). The study, now completed, enrolled PNH patients receiving ravulizumab with zaltenibart added to provide combination therapy for 24 weeks. Those patients demonstrating a hemoglobin response with the combination therapy were then switched to zaltenibart monotherapy. Interim analysis results from the combination therapy stage of the trial were presented at the annual meeting of the European Hematology Association in June by Dr. Morag Griffin, an internationally recognized PNH expert from St. James University Hospital in England. Dr. Griffin will also give the ASH presentation showing that zaltenibart monotherapy resulted in sustained and clinically meaningful improvements in hemoglobin levels and absolute reticulocyte counts while preventing both extravascular and intravascular hemolysis.

    - In addition to our end-of-phase-2 meetings with FDA and European regulators as described above, in preparation for potential commercialization of zaltenibart, we also held a successful engagement with the German Federal Joint Committee, or G-BA – the decision-making body in the German healthcare system that specifies which medical treatments are reimbursed by the statutory health insurance funds. The GB-A provided us with productive feedback on the patient-reported-outcome measures, helpful in securing more attractive pricing, that we plan to incorporate in our Phase 3 program for zaltenibart in PNH.

    - In October 2024, we announced that zaltenibart received rare pediatric disease designation from FDA for the treatment of C3G. Companies awarded a rare pediatric disease designation are eligible to receive a rare pediatric disease priority review voucher from FDA when the designated drug's first approval is for the associated indication in the pediatric population. The holder of a priority review voucher is entitled to obtain priority review by FDA of either a BLA or an NDA for a different product and/or indication, reducing the review time and accelerating any granted approval and subsequent market entry by at least four months. The voucher may be used by the original recipient, or it can be sold for use by another company.

- Recent developments regarding OMS527, our phosphodiesterase 7 ("PDE7") inhibitor program focused on addictions and compulsive disorders as well as movement disorders, include:

    - Our lead orally administered PDE7 inhibitor compound is being developed for the treatment of cocaine use disorder ("CUD") with funding from a three-year, $6.69 million grant awarded in April 2023 by the National Institute on Drug Abuse ("NIDA"). A grant-funded preclinical cocaine interaction study is nearing completion, with results expected later this year. Assuming the results support further development, we expect next year to initiate a randomized, placebo-controlled, inpatient clinical study evaluating the safety and effectiveness of OMS527 in patients with CUD, also funded by the NIDA award.

    - As previously disclosed, we are exploring the potential use of OMS527 in movement disorders, specifically levodopa-induced dyskinesias, or LID.

- Recent developments regarding our oncology platform comprising signaling-driven immunomodulators, oncotoxins, and an adoptive T-cell technology combined with an immunostimulator, include:

    - *In vitro* and *in vivo* studies are rapidly advancing and support the potential of our oncology platform to deliver broadly effective and safe cancer treatments for both hematological and solid tumors to overcome the shortcomings of currently marketed therapies while expanding our intellectual property estate.

    - We have begun raising the visibility of our "stealth" oncology programs, starting at the annual meeting of the Society of Immunotherapy of Cancer in Houston earlier this week and at the upcoming ASH meeting in San Diego. We plan to share further information on these programs publicly in the coming months.

Financial Results

Net loss for the third quarter of 2024 was $32.2 million, or $0.56 per share, compared to a net loss of $37.8 million, or $0.60 per share for the third quarter of 2023. For the nine months ended September 30, 2024, our net loss was $125.5 million, or $2.15 per share, compared to a net loss of $108.8 million, or $1.73 per share in the prior year period. The nine months ended September 30, 2024 includes an $18.4 million charge for narsoplimab drug substance that was delivered, the manufacturing of which commenced in October 2023, a $21.2 million payment for debt repurchase, and $1.9 million of costs related to the debt transaction. We expense all manufacturing activities until U.S. or European approval is reasonably assured.

At September 30, 2024, we had $123.2 million of cash and short-term investments available for operations and debt service, a decrease of $48.7 million from December 31, 2023.

For the third quarter of 2024, we earned OMIDRIA royalties of $9.3 million on Rayner's U.S. net sales of $31.0 million. This compares to earned OMIDRIA royalties of $10.0 million during the third quarter of 2023 on U.S. net sales of $33.3 million.

Total operating expenses for the third quarter of 2024 were $35.4 million compared to $48.2 million for the third quarter of 2023. The decrease was primarily due to paying a third-party licensor $5.0 million in the prior year in connection with achievement of a development milestone in our zaltenibart program, decreased clinical expenditures on narsoplimab due to the termination of our clinical program developing narsoplimab for IgA nephropathy and decreased employee compensation expenses in the current year.

Interest expense during the third quarter of 2024 was $4.1 million compared to $7.9 million during the prior year quarter. The decrease was due to retiring the 2023 convertible notes in November 2023 and repurchasing and retiring the majority of the 2026 Notes in December 2023 and June 2024.

During the third quarter of 2024, we earned $2.3 million in interest and other income compared to $4.4 million in the third quarter of 2023. The difference is primarily due to lesser cash and investments available to invest in the third quarter.

Net income from discontinued operations, net of tax, was $4.9 million, or $0.08 per share, in the third quarter of 2024 compared to $13.9 million, or $0.22 per share, in the third quarter of 2023. The decrease was primarily attributable to a higher remeasurement adjustment taken in the prior year quarter on the OMIDRIA contract royalty asset offset by increased non-cash interest earned.

Conference Call Details

Omeros' management will host a conference call and webcast 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.

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

To access the live conference call via phone, participants must register at the following URL https://register.vevent.com/register/BIf3c1eb9c93ae411eac97126f51f6c200 to receive a unique PIN. 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.

A replay of the call will be made accessible online at https://investor.omeros.com/archived-events.

About Omeros Corporation

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing first-in-class small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders, including complement-mediated diseases and cancers, as well as 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. Omeros' long-acting MASP-2 inhibitor OMS1029 has successfully completed Phase 1 single- and multiple-ascending dose clinical studies. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is advancing toward Phase 3 clinical trials for paroxysmal nocturnal hemoglobinuria and complement 3 glomerulopathy. Funded by the National Institute on Drug Abuse, Omeros' lead phosphodiesterase 7 inhibitor OMS527 is in clinical development for the treatment of cocaine use disorder. Omeros also is advancing a broad portfolio of five novel cellular and molecular immuno-oncology programs. 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 the anticipated next steps in relation to the biologics license application for narsoplimab, the timing of regulatory events, the availability of clinical trial data, the prospects for obtaining FDA approval of narsoplimab in any indication, expectations regarding the initiation or continuation of clinical trials evaluating Omeros' drug candidates and the anticipated availability of data therefrom, expectations regarding future cash expenditures, and expectations regarding the sufficiency and availability of our capital resources to fund current and planned operations, 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, our financial condition and results of operations, regulatory processes and oversight, challenges associated with manufacture or supply of our products to support clinical trials, regulatory process and/or commercial sale following any marketing approval, changes in reimbursement and payment policies by government and commercial payers or the application of such policies, failure by Congress to reauthorize the priority review voucher program or other legislative developments, intellectual property claims, competitive developments, litigation, and the risks, uncertainties and other factors described under the heading "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2024, an in our subsequently filed 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 we assume 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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Investor and Media Relations
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OMEROS CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Costs and expenses:				
Research and development	$ 24,084	$ 31,731	$ 96,203	$ 85,980
Selling, general and administrative	11,323	16,422	37,395	38,785
Total costs and expenses	35,407	48,153	133,598	124,765
Loss from operations	(35,407)	(48,153)	(133,598)	(124,765)
Interest expense	(4,052)	(7,916)	(21,498)	(23,781)
Interest and other income	2,346	4,413	9,008	12,913
Net loss from continuing operations	(37,113)	(51,656)	(146,088)	(135,633)
Net income from discontinued operations, net of tax	4,881	13,906	20,631	26,888
Net loss	$ (32,232)	$ (37,750)	$ (125,457)	$ (108,745)
Basic and diluted net income (loss) per share:				
Net loss from continuing operations	$ (0.64)	$ (0.82)	$ (2.51)	$ (2.16)
Net income from discontinued operations	0.08	0.22	0.36	0.43
Net loss	$ (0.56)	$ (0.60)	$ (2.15)	$ (1.73)
Weighted-average shares used to compute basic and diluted net income (loss) per share	57,948,093	62,856,721	58,232,007	62,840,990

OMEROS CORPORATION

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEET

(In thousands)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 1,521	$ 7,105
Short-term investments	121,636	164,743
OMIDRIA contract royalty asset, short-term	29,243	29,373
Receivables	6,394	8,096
Prepaid expense and other assets	6,127	8,581
Total current assets	164,921	217,898
OMIDRIA contract royalty asset	129,488	138,736
Right of use assets	15,933	18,631
Property and equipment, net	1,939	1,950
Restricted investments	1,054	1,054
Total assets	$ 313,335	$ 378,269
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 7,723	$ 7,712
Accrued expenses	23,246	31,868
OMIDRIA royalty obligation, current	18,884	8,576
Lease liabilities, current	5,770	5,160
Total current liabilities	55,623	53,316
Convertible senior notes, net	97,032	213,155
Long-term debt, net	92,427	—
OMIDRIA royalty obligation, non-current	205,089	116,550
Lease liabilities, non-current	14,242	18,143
Other accrued liabilities, non-current	3,094	2,088
Shareholders' equity (deficit):		
Common stock and additional paid-in capital	724,815	728,547
Accumulated deficit	(878,987)	(753,530)
Total shareholders' deficit	(154,172)	(24,983)
Total liabilities and shareholders' equity (deficit)	$ 313,335	$ 378,269