



NEWS RELEASE

Omeros Corporation Reports Fourth Quarter and Year-End 2024 Financial Results

2025-03-31

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

SEATTLE--(BUSINESS WIRE)--Mar. 31, 2025-- Omeros Corporation (Nasdaq: OMER) today announced recent highlights and developments as well as financial results for the fourth quarter and year ended December 31, 2024, which include:

- Net loss for the fourth quarter of 2024 was \$31.4 million, or \$0.54 per share, compared to a net loss of \$32.2 million, or \$0.56 per share for the third quarter of 2024.
- For the year ended December 31, 2024, net loss was \$156.8 million, or \$2.70 per share, compared to a net loss of \$117.8 million, or \$1.88 per share in the prior year. The change in net loss reflects a \$33.2 million decrease in the noncash gain from the remeasurement of the OMIDRIA contract royalty asset, a \$6.6 million decrease in interest income earned and a \$4.1 million gain on the early extinguishment of debt in December 2023, which were partially offset by a \$6.2 million decrease in interest expense as a result of our debt repurchases and refinancing.
- At December 31, 2024, we had \$90.1 million of cash and short-term investments available for operations and debt servicing, a decrease of \$81.7 million from December 31, 2023. We incurred significant cost outlays during the year representing a total of \$42.7 million. These cost outlays are comprised of \$21.7 million in payments related to repurchasing our convertible senior notes maturing in 2026, \$19.1 million in charges

related to delivery of narsoplimab drug substance and \$1.9 million of costs related to our senior debt transaction.

- Earlier this month, we successfully resubmitted 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 resubmitted BLA includes the previously announced results of a protocol and statistical analysis plan that we developed with input from FDA to compare survival in TA-TMA patients treated with narsoplimab to survival in an external control population of TA-TMA patients who did not receive narsoplimab. We expect the target date for FDA action under the Prescription Drug User Fee Act (“PDUFA”) to be six months following the date of resubmission to FDA, meaning, in this case, the PDUFA date would be in September 2025.
- We expect to submit our European marketing authorization application (“MAA”) for narsoplimab in TA-TMA in the first half of 2025. The European Medicines Agency (“EMA”) has appointed rapporteurs from Germany and Austria responsible to coordinate review by EMA’s Committee for Human Medicinal Products of the anticipated MAA for narsoplimab. At upcoming meetings scheduled with representatives from both rapporteur countries, Omeros will orient the representatives to the data included in the application. EMA has confirmed narsoplimab’s eligibility for centralized review of a single MAA that, if approved, authorizes the product to be marketed in all EU member states and European Economic Area countries.
- Site activation has begun in our Phase 3 development program evaluating zaltenibart (formerly known as OMS906), our lead MASP-3 antibody targeting the key and most proximal activator of the alternative pathway of complement, for the treatment of paroxysmal nocturnal hemoglobinuria (“PNH”). Similar to our Phase 2 program in this indication, our Phase 3 program includes a study treating PNH patients who are not receiving a complement-inhibitor, as well as a “switch-over” study in PNH patients who have had an unsatisfactory response to ravulizumab, an inhibitor of complement component 5 (“C5”).

“We are pleased to announce that our narsoplimab BLA for the treatment of TA-TMA was resubmitted to FDA earlier this month, with the MAA slated for European submission in the coming quarter,” stated Gregory A. Demopoulos, M.D., Chairman and CEO of Omeros. “All study results in the BLA are uniformly strong across all comparative analyses and all datasets – the primary and primary-related sensitivity analyses, the 136-patient expanded access program, adults and children, and patients who had failed treatment with other off-label agents prior to receiving narsoplimab. With a six-month review cycle from the date of resubmission, we look forward to working closely with FDA toward narsoplimab’s approval and our commercial team is well-prepared to execute a successful market launch. Zaltenibart’s compelling results in our Phase 2 PNH trials are highly predictive of the similarly designed and ongoing Phase 3 program in PNH, which remains on track to readout data late next year, and we are focused on establishing ex-U.S. partnerships for both zaltenibart and narsoplimab. Also later this year, we expect data from our NIDA-funded OMS527 trial in patients with cocaine use disorder. Collectively, these programs in BLA review and with near-term clinical trial results translate to significant shareholder value.”

Fourth Quarter and Recent Clinical Developments

- Recent developments regarding our program targeting mannan-binding lectin-associated serine protease-2 (“MASP-2”) and the lectin pathway of complement include the following:
 - The BLA for narsoplimab resubmitted to FDA in March 2025 includes the results of a protocol and statistical analysis plan that we developed with input from FDA, including final comments received subsequent to our most recent meeting with the agency in September 2024. The primary endpoint under the analysis plan is patient survival in our pivotal narsoplimab trial (OMS721-TMA-001) compared to that in an external registry of TA-TMA patients who were not treated with narsoplimab. Analyses similar to the primary analysis comparing survival in TA-TMA patients treated with narsoplimab under our global expanded access program (“EAP”) to that of similarly at-risk TA-TMA registry patients were also included in the analysis plan, along with sensitivity analyses related to each of the primary and EAP comparisons. All statistical analyses were conducted by an independent statistical group and the results were previously announced.
 - Narsoplimab met its primary statistical analysis endpoint comparing overall survival in the 28 TA-TMA patients in the pivotal trial for narsoplimab in TA-TMA (OMS721-TMA-001), to that of more than 100 similarly high-risk TA-TMA patients in an external control registry of TA-TMA patients who did not receive narsoplimab treatment. OMS721-TMA-001 patients demonstrated clinically meaningful and statistically significant superiority in overall survival – a hazard ratio of 0.32 (95% confidence interval: 0.23 to 0.44) with p-value less than 0.00001 – compared to the TA-TMA patients in the external registry.
 - The EAP-related analyses, which comprise multiple survival comparisons between narsoplimab-treated EAP patients and similarly at-risk TA-TMA patients in the external control registry, further support the robustness of the primary analysis results, with representative analyses of the combined EAP and pivotal trial patients yielding hazard ratios ranging from 0.34 (95% confidence interval: 0.21, 0.53) to 0.46 (95% confidence interval: 0.35, 0.60) and p-values ranging from less than 0.00001 to 0.00002.
 - Results of the primary-related and EAP-related sensitivity analyses performed as part of the statistical analysis plan support the robustness of the primary results. The EAP includes adults and children and includes both treatment-naïve patients and patients who failed or stopped treatment for their TA-TMA prior to receiving narsoplimab. Analyses of survival across all of these subgroups of patients treated with narsoplimab show consistently impressive survival results regardless of age or prior treatment status.
 - Last month, two presentations reporting real world outcomes from TA-TMA patients treated with narsoplimab supplied by Omeros under the EAP were featured at the 2025 Tandem Meetings – the

Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy and the Center for International Blood and Marrow Transplant Research held February 12-15, 2025 in Honolulu, Hawaii. The first, a podium presentation, reported on the impressive survival in both adult and pediatric high-risk TA-TMA patients, including those who had failed one or more other TA-TMA-directed therapies (primarily eculizumab) prior to receiving narsoplimab. The second reported on high-risk TA-TMA patients who had failed eculizumab and were subsequently treated with narsoplimab, achieving an over three-fold increase in one-year survival compared to the reported survival in eculizumab-refractory patients of 20 percent or less.

- Panels of leading international transplant experts have drafted two manuscripts directed to survival of narsoplimab-treated TA-TMA patients, which are under review and will be submitted for publication in premier peer-reviewed journals once finalized. The first compares survival in patients in the narsoplimab pivotal trial to survival in the same external control population of TA-TMA patients used in our BLA primary analysis and the second will detail the survival data in the 50 pediatric TA-TMA patients treated with narsoplimab under our expanded access program.
- We continue to explore the potential of narsoplimab and MASP-2 inhibition in severe acute respiratory distress syndrome ("ARDS") and have generated compelling data from established animal models across bacterial, viral and chemical-induced forms of ARDS. This work includes an ongoing study in animals infected with H5N1 avian influenza or "bird flu," which some experts regard as a threat to become a global pandemic. A manuscript has already been drafted and awaits receipt of the H5N1 data. We also continue to advance 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.
- We are identifying indications for our Phase 2 clinical development of OMS1029, our long-acting, next-generation MASP-2 inhibitor. OMS1029 drug product has been manufactured and stored in quantities sufficient to support a future Phase 2 clinical trial. Single- and multiple-ascending-dose Phase 1 studies of OMS1029 were previously completed and validate once quarterly subcutaneous administration of OMS1029 to effectively ablate MASP-2 activity in humans. OMS1029 has been well tolerated to date with no safety concerns identified.
- 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:
 - We have initiated our Phase 3 clinical program for zaltenibart in PNH, which is comprised of two studies: one treating PNH patients who are not receiving a complement-inhibitor, and the other treating PNH patients who have had an unsatisfactory response to the C5 inhibitor ravulizumab and utilizing a "switch-over" design similar to our Phase 2 study. Both studies in our Phase 3 program are designed to provide head-to-head comparisons with the C5 inhibitors and could produce data demonstrating the superiority of zaltenibart over the C5 inhibitors in these patient populations. These data would

potentially form the basis for comparative superiority claims for promotion, enhanced market access, and pricing reflective of zaltenibart's advantages.

- 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 were presented in December 2024 at the Annual Meeting of the American Society of Hematology. 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. Twelve of 13 enrolled patients continued to the monotherapy stage of the study. The interim results showed that in PNH patients experiencing substantial extravascular hemolysis while receiving ravulizumab, zaltenibart monotherapy resulted in sustained clinically meaningful improvements in both hemoglobin and absolute reticulocyte count and prevented both intravascular and extravascular hemolysis.
- Our Phase 2 clinical trial evaluating zaltenibart in C3 glomerulopathy ("C3G") is also open to enrollment in multiple countries and dosing in the study is ongoing. This study requires enrollment of a relatively small number of patients. Following completion of the Phase 2 study, and assuming strong evidence of efficacy, we plan to initiate a Phase 3 trial in C3G.
- Recent developments regarding OMS527, our phosphodiesterase 7 ("PDE7") inhibitor program focused on addictions and compulsive disorders as well as movement disorders, include:
 - In March 2025, the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health confirmed its funding commitment for the upcoming year commencing April 1, 2025 in the amount of \$4.02 million. This amount, part of a grant originally awarded in April 2023 to support development at NIDA's direct request of our lead orally administered PDE7 inhibitor compound for the treatment of cocaine use disorder ("CUD"), is expected to fund an inpatient clinical trial assessing safety and efficacy of OMS527 in adult patients with CUD. The funding commitment followed the successful completion of NIDA-funded OMS527-cocaine interaction safety studies in which OMS527 was co-administered with cocaine in two animal species to rule out enhancement of the detrimental effects of cocaine.
 - In the OMS527-cocaine interaction studies, OMS527, when administered at two different doses in combination with cocaine did not enhance the adverse cocaine effects in rats or non-human primates. Instead, the higher doses of OMS527 generally lessened the severity of effects noted following intravenous administration of cocaine, most notably decreasing convulsant-related activity following the administration of cocaine.
 - Work on the planned randomized, double-blind, parallel-group, inpatient Phase 1b clinical trial comparing the safety and efficacy of OMS527 to placebo in the treatment of adults with CUD is underway, and a preliminary data readout from that study is targeted by year-end 2025.
- 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 to overcome the shortcomings of currently marketed therapies. These programs are currently operating in “stealth” mode while we continue to secure our intellectual property estate around these technologies. Over the past several months we have engaged in confidential discussions to seek input and guidance from leading therapeutic-area experts and their uniformly positive response has been encouraging. We plan to share further information on these programs publicly in the near term.

Financial Results

Net loss for the fourth quarter of 2024 was \$31.4 million, or \$0.54 per share, compared to a net loss of \$32.2 million, or \$0.56 per share for the third quarter of 2024.

For the year ended December 31, 2024, our net loss was \$156.8 million, or \$2.70 per share, compared to a net loss of \$117.8 million, or \$1.88 per share in the prior year period. The change in net loss reflects a \$33.2 million decrease in the noncash gain from the remeasurement of the OMIDRIA contract royalty asset, a \$6.6 million decrease in interest income earned and a \$4.1 million gain on the early extinguishment of debt in December 2023, which were partially offset by a \$6.2 million decrease in interest expense as a result of our debt repurchases and refinancing.

At December 31, 2024, we had \$90.1 million of cash and short-term investments available for operations and debt service, a decrease of \$81.7 million from December 31, 2023. We incurred significant cost outlays during the year representing a total of \$42.7 million. These cost outlays are comprised of \$21.7 million in payment related to repurchasing our convertible senior notes maturing in 2026, \$19.1 million in charges related to delivery of narsoplimab drug substance and \$1.9 million of costs related to our senior credit transaction. Our cash used in operations for the fourth quarter was \$29.0 million.

For the fourth quarter of 2024, we earned OMIDRIA royalties of \$10.1 million on Rayner’s U.S. net sales of \$33.6 million. This compares to earned OMIDRIA royalties of \$9.3 million during the third quarter of 2024 on U.S. net sales of \$31.0 million.

Total operating expenses for the fourth quarter of 2024 were \$35.7 million compared to \$35.4 million for the third quarter of 2024.

Interest expense during the fourth quarter of 2024 was \$3.2 million compared to \$4.1 million during the prior quarter. The decrease was primarily due to the remeasurement of the OMIDRIA royalty obligation.

We earned \$2.3 million, respectively, for both the fourth and third quarters of 2024 in interest and other income.

Net income from discontinued operations, net of tax, was \$5.2 million for the fourth quarter of 2024 compared to \$4.9 million in the prior quarter.

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-conf.media-server.com/register/Blfd61371fd0fb44c1a0e7bdc80c36e0f8> 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. Zaltenibart, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is in Phase 3 clinical development for paroxysmal nocturnal hemoglobinuria and is being evaluated in an ongoing Phase 2 clinical trial for 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 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 PDUFA date for FDA review of the biologics license application for narsoplimab, the anticipated submission to EMA of a marketing authorization application for narsoplimab, the prospects for obtaining FDA or EMA 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 including the potential commercialization of narsoplimab if it is approved by FDA or EMA, 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, unfavorable or unexpected interpretation of our statistical analyses relating to an external registry of TA-TMA patients, potential differences between the diagnostic criteria used in our pivotal trial and in the external registry, and whether FDA and the EMA determine the registry used in our statistical analysis is sufficiently representative of TA-TMA patients, unanticipated or unexpected outcomes of regulatory processes in relevant jurisdictions, unproven preclinical and clinical development activities, our financial condition and results of operations and our ability to raise capital when necessary to continue our operations, regulatory processes and oversight, challenges associated with manufacture or supply of our products to support clinical trials, regulatory inspections 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, 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 March 31, 2025, and 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.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2024	2023	2024	2023
Costs and expenses:				
Research and development	\$23,320	\$28,890	\$119,523	\$114,870
Selling, general and administrative	12,340	10,875	49,735	49,660
Total costs and expenses	35,660	39,765	169,258	164,530
Loss from operations	(35,660	) (39,765	) (169,258	) (164,530
Interest expense	(3,177	) (7,063	) (24,675	) (30,844
Interest and other income	2,296	3,429	11,304	16,342
Gain on early extinguishment of convertible senior notes	—	4,112	—	4,112
Net loss from continuing operations	(36,541	) (39,287	) (182,629	) (174,920
Net income from discontinued operations, net of tax	5,183	30,219	25,814	57,107
Net loss	\$(31,358	) \$(9,068	) \$(156,815	) \$(117,813
Basic and diluted net income (loss) per share:				
Net loss from continuing operations	\$(0.63	) \$(0.63	) \$(3.14	) \$(2.79
Net income from discontinued operations	0.09	0.48	0.44	0.91
Net loss	\$(0.54	) \$(0.15	) \$(2.70	) \$(1.88
Weighted-average shares used to compute basic and diluted net income (loss) per share	57,987,961	62,440,772	58,170,931	62,739,227

OMEROS CORPORATION

UNAUDITED CONSOLIDATED BALANCE SHEET

(In thousands)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,400	\$ 7,105
Short-term investments	86,732	164,743
OMIDRIA contract royalty asset, short-term	29,083	29,373
Receivables	7,739	8,096
Prepaid expense and other assets	7,166	8,581
Total current assets	134,120	217,898
OMIDRIA contract royalty asset	124,266	138,736
Right of use assets	14,961	18,631
Property and equipment, net	2,678	1,950
Restricted investments	1,054	1,054
Total assets	\$ 277,079	\$ 378,269

Liabilities and shareholders' equity (deficit)

Current liabilities:		
Accounts payable	\$ 5,905	\$ 7,712
Accrued expenses	26,005	31,868
OMIDRIA royalty obligation, current	20,645	8,576
Current portion of term debt	21,000	—

Lease liabilities, current	5,971		5,160	
Total current liabilities	79,526		53,316	
OMIDRIA royalty obligation, non-current	195,612		116,550	
Convertible senior notes, net	97,178		213,155	
Long-term debt, net	69,405		—	
Lease liabilities, non-current	13,466		18,143	
Other accrued liabilities, non-current	4,501		2,088	
Shareholders' equity (deficit):				
Common stock and additional paid-in capital	727,736		728,547	
Accumulated deficit	(910,345	)	(753,530	)
Total shareholders' deficit	(182,609	)	(24,983	)
Total liabilities and shareholders' equity (deficit)	\$ 277,079		\$ 378,269	

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