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): March 13, 2023

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 March 13, 2023, Omeros Corporation issued a press release announcing financial results for the three months and year ended December 31, 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 March 13, 2023, pertaining to Omeros Corporation's financial results for the three months and year ended December 31, 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: March 13, 2023

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

Omeros Corporation Reports Fourth Quarter and Year-End 2022 Financial Results

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

SEATTLE, WA – March 13, 2023 – Omeros Corporation (Nasdaq: OMER), a clinical-stage 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, today announced recent highlights and developments as well as financial results for the fourth quarter and year ended December 31, 2022, which include:

- Net income in the fourth quarter of 2022 was $128.7 million, or $2.05 per share, compared to a net loss in the third quarter of 2022 of $17.5 million, or $0.28 per share; our fourth quarter's net loss from continuing operations was $46.0 million, or $0.73 per share, compared to $54.8 million, or $0.87 per share, in the third quarter of 2022. Cash burn for the fourth quarter of 2022 was $26.0 million.

- For the year ended December 31, 2022, net income was $47.4 million, or $0.76 per share. This compares to net income of $194.2 million or $3.12 per share for the year ended December 31, 2021.

- The milestone event specified in the asset purchase agreement by which we sold our former ophthalmology product OMIDRIA® to Rayner Surgical, Inc. ("Rayner") occurred in December 2022, resulting in us recording as a receivable the $200.0 million milestone payment from Rayner in December 2022 and receiving the cash payment in February 2023.

- For the fourth quarter ended December 31, 2022, we earned OMIDRIA royalties of $17.9 million on Rayner's U.S. net sales of $35.8 million, an all-time high for quarterly net sales of OMIDRIA. This compares to earned royalties of $16.5 million during the third quarter of 2022. For the year ended December 31, 2022, we earned royalties of $65.4 million on U.S. net sales of OMIDRIA.

- At December 31, 2022, we had $194.9 million of cash, cash equivalents and short-term investments. In addition, we had $213.2 million of accounts receivable, substantially all of which have been collected. We do not have any assets on deposit with Silicon Valley Bank nor do we have any other financial relationship with the bank or its affiliated entities.

- The Consolidated Appropriations Act of 2023 ("CAA") was signed into law in late December 2022 and expressly provides for separate payment of non-opioid pain management drugs, like OMIDRIA, in the outpatient surgery setting until January 1, 2028.

- We are preparing to resubmit our Biologics License Application ("BLA") for narsoplimab in hematopoietic stem cell transplant-associated thrombotic microangiopathy ("TA-TMA") and have requested a meeting with FDA, expected to be held next quarter, to confirm the additional information required by FDA to support approval.

- We have initiated two clinical trials evaluating OMS906, one enrolling patients with paroxysmal nocturnal hemoglobinuria ("PNH") who are treatment-naïve and the other enrolling PNH patients who have demonstrated an unsatisfactory response to ravulizumab; dosing is ongoing in the first and initiating in the second.

"With over $400 million available for operations and having secured our ongoing OMIDRIA royalty stream, Omeros now has the flexibility to retire our 2023 debt obligation while funding accelerated advancement across our portfolio of

cutting-edge platforms and programs well into 2025. Any additional revenue source – for which there are multiple opportunities – would only extend that runway, further driving shareholder value without the need for dilution," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "For narsoplimab, we are meeting with FDA to confirm the information required for approval of our resubmitted BLA for TA-TMA, we remain on track for third-quarter release of topline data from our pivotal ARTEMIS-IGAN trial, and there is mutual interest in working with the U.S. government in COVID-19 and ARDS. Our long-acting MASP-2 inhibitor OMS1029 looks promising in the clinic for quarterly IV or SC administration and, together with our orally available small-molecule inhibitors, complements narsoplimab and expands our control over the lectin pathway. OMS906, targeting the key activator of the alternative pathway MASP-3, we expect can also be dosed once quarterly and, given its significant biological advantages over potential competitors, pending efficacy data in PNH followed by C3G will go a long way in answering whether MASP-3 and OMS906 are the premier alternative-pathway target and therapeutic. We also are hoping for good news over the coming weeks on our PDE7 inhibitor OMS527 in both addiction and in Parkinson's disease. And our novel molecular and cellular immuno-oncology platforms and programs continue to generate exciting data that consistently point to the same conclusion – the potential for transformative cancer therapies. All of our portfolio programs could well be successful, but the success of any one of them would deliver substantial shareholder value."

Fourth 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 and immunoglobulin A ("IgA") nephropathy, include:
    - Preparations are underway for anticipated resubmission of our BLA for narsoplimab in TA-TMA following the late-2022 receipt of the decision by FDA's Office of New Drugs regarding our appeal of FDA's complete response letter previously issued on our original BLA. The decision denying our appeal proposed, as a path forward for BLA resubmission, the inclusion of additional analyses comparing response and survival in our completed pivotal trial to appropriate historical controls. We have requested a meeting with FDA's Division of Nonmalignant Hematology to confirm the information required by FDA to support approval of narsoplimab in this indication. We expect that the Type B meeting will occur in the first half of the second quarter of 2023.
    - Our Phase 3 ARTEMIS-IGAN trial evaluating narsoplimab for the treatment of IgA nephropathy continues to progress toward an anticipated readout of 9-month data on the proteinuria endpoint in the third quarter of 2023.
    - An international group of leading transplanters recently published a systematic review of signs and symptoms of TA-TMA in *Transplantation and Cellular Therapy*, and a second manuscript on TA-TMA diagnosis and treatment has been accepted for publication by *Bone Marrow Transplantation*.
- Recent developments regarding OMS1029, our long-acting, next-generation MASP-2 inhibitor, include:
    - Dosing of all cohorts in a single-ascending dose Phase 1 clinical trial of OMS1029 was successfully completed in early 2023. OMS1029 was well tolerated with no safety concerns identified. Preliminary pharmacokinetic ("PK") and pharmacodynamic ("PD") data show dose-proportional exposure and sustained lectin pathway inhibition, consistent with potentially quarterly intravenous or subcutaneous dosing.
    - Preparations are underway to initiate, in summer 2023, a Phase 1 multiple-ascending-dose study of OMS1029 in healthy subjects.
- Recent developments regarding OMS906, our lead monoclonal antibody targeting mannan-binding lectin-associated serine protease-3 ("MASP-3"), the key activator of the alternative pathway, include:
    - Clinical data from our single-ascending-dose Phase 1 study evaluating both intravenous and subcutaneous administration of OMS906 in healthy subjects were presented in December at the annual meeting of the American Society of Hematology. As previously announced, the drug was well tolerated, and there were

no safety signals of concern. Based on clinical data to date, we expect that OMS906 will be dosed quarterly, either intravenously or subcutaneously.

- In late 2022 we began enrolling in our Phase 1b clinical trial evaluating OMS906 in treatment-naïve patients with PNH. Dosing in this study began in early 2023.

- Enrollment has also begun in our Phase 1b clinical trial evaluating OMS906 in PNH patients who have had an unsatisfactory response to the C5 inhibitor ravulizumab. The study enrolls PNH patients receiving ravulizumab, adds OMS906 to provide combination therapy with ravulizumab for 24 weeks, and then provides OMS906 monotherapy in patients who demonstrate a hemoglobin response with combination therapy. First dosing of OMS906 in this study is scheduled to begin later this month, once the ravulizumab monotherapy period has ended.

- A Phase 1b clinical trial evaluating OMS906 in patients with complement 3 glomerulopathy ("C3G") has also been initiated, with enrollment expected to commence next month.

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

  - We are engaged in discussions with third parties regarding external funding for development of our PDE7 inhibitors as a treatment for addictive disorders.

  - OMS527 is also being evaluated as a potential treatment for levodopa-induced dyskinesias ("LID"), which are crippling, involuntary movements reportedly affecting 50 percent or more of levodopa-treated patients with Parkinson's disease. LID is caused by prolonged treatment with levodopa, the most prescribed treatment for Parkinson's. Collaborators at Emory University are evaluating our PDE7 inhibitor in a clinically predictive primate model of LID.

Financial Results

Net income for the fourth quarter of 2022 was $128.7 million, or $2.05 per share, which includes the $200.0 million milestone recognized as income in discontinued operations. This compares to a net loss of $17.5 million in the third quarter of 2022, or $0.28 per share. Net loss from continuing operations for the fourth quarter of 2022 was $46.0 million, or $0.73 cents per share. For the third quarter of 2022, net loss from continuing operations was $54.8 million, or $0.87 per share. Cash burn for the fourth quarter of 2022 was $26.0 million.

Net income for the full year 2022 was $47.4 million, or $0.76 per share, and our net loss from continuing operations was $182.0 million or $2.90 per share. This compares to the prior full year's net income of $194.2 million, or $3.12 per share, and a loss from continuing operations of $191.5, or $3.07 per share.

In December 2022, the milestone event entitling us to a $200.0 million milestone payment from Rayner occurred. We recorded the $200.0 million milestone as revenue in discontinued operations and as a receivable in December 2022. We received the cash payment on February 3, 2023. Per the terms of the asset purchase agreement with Rayner, following the milestone event the applicable royalty rate was reduced to 30% of the net revenue from U.S. sales of OMIDRIA. Upon achieving the $200.0 million milestone, we conservatively revalued the OMIDRIA contract royalty asset using the reduced royalty rate of 30% on future OMIDRIA U.S. net sales while reflecting an increase in expected OMIDRIA U.S. net sales due to the CAA securing separate payment for drugs like OMIDRIA until at least January 1, 2028. This remeasurement resulted in a $26.2 million reduction in the OMIDRIA contract royalty asset and a corresponding loss being recorded in discontinued operations in the fourth quarter.

During the fourth quarter of 2022, we earned royalties of $17.9 million on $35.8 million of Rayner sales of OMIDRIA. This compares to earned royalties of $16.5 million in the third quarter of 2022. These royalties were recorded as a reduction of the OMIDRIA contract royalty asset.

Total costs and expenses for the fourth quarter of 2022 were $40.1 million compared to $50.8 million for the third quarter of 2022. The decrease was primarily due to the manufacturing of narsoplimab drug substance in the third quarter of 2022 for future commercial and clinical use. We expense commercial drug substance until approval is assured.

Interest expense during the fourth quarter of 2022 was $7.9 million, an increase of $3.0 million from the third quarter of 2022. On September 30, 2022, we sold to DRI Healthcare Acquisitions LP an interest in a portion of our future OMIDRIA royalty receivables and received $125.0 million in cash proceeds. The transaction was recorded as debt for financial reporting purposes with an implied interest rate of 9.4%.

Net income from discontinued operations, net of tax was $174.8 million, or $2.78 per share, in the fourth quarter of 2022 compared to net income from discontinued operations, net of tax of $37.3 million, or $0.59 per share, in the prior quarter. The increase was primarily due to the $200.0 milestone we earned in the fourth quarter, partially offset by the milestone-driven revaluation of the OMIDRIA contract royalty asset.

As of December 31, 2022, we had $194.9 million of cash, cash equivalents and short-term investments. In addition, we had $213.2 million in accounts receivable, all of which have now been collected. We previously maintained a line of credit with Silicon Valley Bank, which we allowed to expire in August 2022. We do not have any assets on deposit with Silicon Valley Bank nor do we have any other financial relationship with the bank or its affiliated entities

Conference Call Details

To access the live conference call via phone, participants must register to receive a unique PIN at the following URL: https://register.vevent.com/register/BIb42f849906d44aaea742e6f375a5609e.

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 the investor page of 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 anticipated next steps in relation to the biologics license application for narsoplimab, 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 of OMIDRIA, 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 13, 2023. 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

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(In thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Costs and expenses:				
Research and development	$ 26,550	$ 30,327	$ 112,721	$ 118,775
Selling, general and administrative	13,589	12,560	50,668	54,842
Total costs and expenses	40,139	42,887	163,389	173,617
Loss from continuing operations	(40,139)	(42,887)	(163,389)	(173,617)
Interest expense	(7,902)	(4,949)	(22,702)	(19,669)
Interest and other income	1,993	526	4,062	1,740
Net loss from continuing operations	(46,048)	(47,310)	(182,029)	(191,546)
Net income from discontinued operations, net of tax [1]	174,781	327,930	229,446	385,781
Net income	$ 128,733	$ 280,620	$ 47,417	$ 194,235
Basic and diluted net income (loss) per share:				
Net loss from continuing operations	$ (0.73)	$ (0.76)	$ (2.90)	$ (3.07)
Net income from discontinued operations [1]	2.78	5.24	3.66	6.19
Net income	$ 2.05	$ 4.48	$ 0.76	$ 3.12
Weighted-average shares used to compute basic and diluted net income (loss) per share	62,762,932	62,552,395	62,737,091	62,344,100

(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 months and year ended December 31, 2021 in our financial statements.

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET
(In thousands)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 11,009	$ 100,808
Short-term investments	183,909	56,458
OMIDRIA contract royalty asset, short-term	28,797	44,319
Receivables, net	213,221	38,155
Prepaid expense and other assets	6,300	8,216
Total current assets	443,236	247,956
OMIDRIA contract royalty asset	123,425	140,251
Right of use assets	21,762	28,276
Property and equipment, net	1,492	1,731
Restricted investments	1,054	1,054
Total assets	$ 590,969	$ 419,268
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 5,989	$ 13,400
Accrued expenses	30,551	33,134
Current portion of unsecured convertible senior notes, net	94,381	—
Current portion of OMIDRIA royalty obligation	1,152	—
Current portion of lease liabilities	4,310	5,255
Total current liabilities	136,683	51,789
Unsecured convertible senior notes, net	220,906	313,458
OMIDRIA royalty obligation	125,126	—
Lease liabilities, non-current	22,426	29,126
Other accrued liabilities - noncurrent	444	1,115
Shareholders' equity:		
Common stock and additional paid-in capital	721,401	706,914
Accumulated deficit	(635,717)	(683,134)
Total shareholders' equity	85,684	23,780
Total liabilities and shareholders' equity	$ 590,969	$ 419,268

OMEROS CORPORATION
UNAUDITED CONSOLIDATED SUPPLEMENTAL DATA
(In thousands)

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

OMIDRIA contract royalty asset at December 31, 2021	$ 184,570
Royalties earned	(65,439)
Interest on OMIDRIA contract royalty asset	18,634
Remeasurement adjustments	14,457
OMIDRIA contract royalty asset at December 31, 2022	$ 152,222

Net income from discontinued operations is as follows:

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
	(In thousands)			
Product sales, net	$ —	$ 30,845	$ —	$ 110,735
Costs and expenses	—	8,592	—	30,631
Gross margin	—	22,253	—	80,104
Gain on sale of OMIDRIA	—	305,648	—	305,648
Milestone payment	200,000	—	200,000	—
Interest on OMIDRIA contract royalty asset	4,895	—	18,634	—
Remeasurement adjustments	(26,174)	—	14,457	—
Other income, net	12	1,035	307	1,035
Income before income tax	178,733	328,936	233,398	386,787
Income tax expense	(3,952)	(1,006)	(3,952)	(1,006)
Net income from discontinued operations, net of tax	$ 174,781	$ 327,930	$ 229,446	$ 385,781