
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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 7, 2013

OMEROS CORPORATION

(Exact name of registrant as specified in its charter)

Washington
(State or other jurisdiction
of incorporation)

001-34475
(Commission
File Number)

91-1663741
(IRS Employer
Identification No.)

201 Elliott Avenue West
Seattle, Washington 98119
(Address of principal executive offices, including zip code)

(206) 676-5000
(Registrant's telephone number, including area code)

(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))
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Item 2.02 Results of Operation and Financial Condition.

On November 7, 2013, Omeros Corporation issued a press release announcing financial results for the three and nine months ended September 30, 2013. 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 the liabilities of 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.

| <u>Exhibit Number</u> | <u>Description</u> |
|---------------------------|--|
| 99.1 | Press release dated November 7, 2013 relating to Omeros’ financial results for the three and nine months ended September 30, 2013. |

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

By: /s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D.

President, Chief Executive Officer, and
Chairman of the Board of Directors

Date: November 7, 2013

EXHIBIT INDEX

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|---------------------------|--|
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Omeros Corporation Reports Third Quarter 2013 Financial Results
— Obtains Additional \$17.4 Million in Cash in 4Q 2013 —

SEATTLE, WA–November 7, 2013–

- *Received \$17.4 million in cash in October 2013*
- *Total operating expenses in 3Q 2013 were \$13.6 million including \$3.2 million in non-cash expenses compared to \$13.3 million including non-cash expenses of \$2.1 million in 2Q 2013*
- *U.S. and European regulators accepted Omeros' OMS302 marketing applications for review*
- *OMS824 and OMS721 Phase 1 clinical programs generated positive data*
- *Increased the number of unlocked orphan GPCRs to 52*

Omeros Corporation (NASDAQ: OMER), a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system, today announced its financial results for the third quarter of 2013.

“Throughout the third quarter of 2013, we continued to make significant strides in development across our pipeline,” stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. “For OMS302, the marketing applications were accepted for review by both the FDA and EMA, and the market launch is planned for the second half of 2014. Our OMS824 program for the treatment of cognitive disorders was granted orphan drug designation by the FDA, generated positive Phase 1 clinical trial results, began enrollment in a Phase 2 trial in patients with schizophrenia and is now initiating a Phase 2 trial in Huntington’s disease. OMS721, our MASP-2 inhibitor, entered a Phase 1 clinical trial from which we reported positive data today, and a Phase 2 trial to evaluate the molecule’s efficacy and safety in patients with thrombotic microangiopathies is planned for early 2014. Preclinically, our GPCR platform continued to identify functionally active compounds against an unprecedented number of orphan receptors, and our addiction and high-risk bleeding programs advanced toward the clinic. Following the close of the quarter, we added over \$17 million to our balance sheet, positioning Omeros to execute on a series of value-driving milestones during the remainder of 2013 and well into 2014.”

Third Quarter and Recent Highlights

- Reported U.S. and European regulators had accepted Omeros’ OMS302 marketing applications for review. OMS302, added to standard irrigation solution used during ophthalmological procedures, is Omeros’ proprietary PharmacoSurgery® product designed to maintain intraoperative mydriasis, prevent miosis and reduce postoperative pain and irritation resulting from cataract and other lens replacement surgery. Omeros is preparing for a planned commercial launch of OMS302 in the second half of 2014.

- Announced that Omeros entered into a settlement agreement with Carolina Casualty Insurance Company, or, CCIC, dated October 2, 2013, related to CCIC's defense of, and coverage obligations owed to, Omeros and its chief executive officer and chairman, Dr. Demopoulos, in previously settled litigation with Omeros' former chief financial officer. The settlement included a release of each party's respective claims in the insurance coverage lawsuit and payment by CCIC of \$12.5 million to Omeros, which was received on October 24, 2013.
- Reported positive clinical data from its Phase 1 clinical program evaluating OMS824, the lead compound from its phosphodiesterase 10 (PDE10) program. OMS824 selectively inhibits PDE10, an enzyme expressed in areas of the brain linked to a wide range of diseases that affect cognition, including Huntington's disease and schizophrenia. Omeros subsequently started a Phase 2 trial evaluating the drug in patients with schizophrenia and plans to start a Phase 2 trial in Huntington's disease in early 2014. OMS824 has received orphan drug designation from the FDA for the treatment of Huntington's disease.
- Reported positive clinical data from its Phase 1 clinical trial of OMS721, the company's lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), an important regulator of the lectin pathway of the immune system. A Phase 2 clinical program to evaluate OMS721 in the treatment of thrombotic microangiopathies (TMAs), a family of disorders that occurs in the microcirculation of the body's organs, most commonly the kidney and brain, is expected to begin enrollment in early 2014.
- Announced that its proprietary Cellular Redistribution Assay technology had "unlocked" six additional Class A orphan G protein-coupled receptors (GPCRs) for drug development, bringing the total number of Class A orphan GPCRs "unlocked" by Omeros to 52. These six orphan GPCRs are linked to a series of important indications, including cardiovascular indications, certain types of cancer and Grave's disease. Omeros also announced that it had identified small molecules that interact with two non-orphan Class B GPCRs, the glucagon-like peptide 1 receptor (GLP-1R) and the parathyroid hormone 1 receptor (PTH-1R). Both of these receptors are established drug targets – GLP-1R for diabetes and PTH-1R for osteoporosis.

Financial Results

Total operating expenses for the quarter ended September 30, 2013 were \$13.6 million and included non-cash expenses of \$3.2 million related to rent expense and stock-based compensation. For the same period in 2012, total operating expenses were \$14.5 million, which included non-cash rent and stock-based compensation expenses of \$576,000.

The decrease in total operating expenses for the quarter ended September 30, 2013 compared to the prior year quarter is primarily due to a litigation settlement expense of \$3.95 million recorded in the same period in 2012, which was reimbursed by CCIC in the fourth quarter of 2012. For the quarter ended September 30, 2013, total (i.e., cash and non-cash) operating expenses, excluding the litigation expense, increased by \$3.1 million compared to the same period in 2012. The increase was primarily due to the non-cash rent and stock-based compensation expenses of \$3.2 million in 3Q 2013 compared to \$576,000 in 3Q 2012. The remaining increases were related to conducting the company's Phase 1 clinical program evaluating OMS824, advancing our MASP-2 program, preparing the New Drug Application (NDA) and Marketing Authorization Application (MAA) for OMS302, planning for the commercial launch of

OMS302 in the second half of 2014, and non-recurring legal expenses incurred in connection with the CCIC matter. These higher costs were partially offset by lower overall clinical trial expenses related to the completion of the company's OMS302 Phase 3 clinical program in January 2013 and the completion of the company's first OMS103HP Phase 3 clinical trial in arthroscopic partial meniscectomy patients in December 2012.

Total revenue for the quarter ended September 30, 2013 was \$196,000 compared to \$1.4 million for the same period in 2012. This decrease was primarily due to lower revenue recognized from the company's GPCR platform development funding agreement with Vulcan Inc. and its affiliate. While research continues under the company's GPCR program, no additional deferred revenue under the Vulcan agreement remains to be recognized after the first quarter of 2013.

For the quarter ended September 30, 2013, Omeros reported a net loss of \$13.9 million, or \$0.46 per share, inclusive of the above-referenced \$3.2 million of non-cash charges equaling \$0.11 per share, compared to a net loss of \$13.3 million, or \$0.51 per share, inclusive of the above-referenced \$576,000 of non-cash charges equaling \$0.02 per share, for the same period in 2012.

At September 30, 2013, Omeros had cash, cash equivalents and short-term investments of \$9.0 million. On October 24, 2013, subsequent to the end of the quarter, Omeros received a payment of \$12.5 million from CCIC pursuant to the terms of the settlement agreement. Omeros also received \$4.9 million in net proceeds from the sale of 373,700 shares of its common stock, sold at an average price of \$13.29 per share, pursuant to the company's at-the-market equity facility in October 2013.

About Omeros Corporation

Omeros is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics targeting inflammation, coagulopathies and disorders of the central nervous system. Derived from its proprietary PharmacoSurgery® platform, the Company's lead drug product, OMS302 for lens replacement surgery, is currently under review for marketing approval by both the US Food and Drug Administration and the European Medicines Agency with commercial launch planned for the second half of 2014. Omeros' five other clinical programs are focused on schizophrenia, Huntington's disease and cognitive impairment; addictive and compulsive disorders; complement-related diseases; and preventing problems associated with surgical procedures. Omeros also has a proprietary GPCR platform, which is making available an unprecedented number of new GPCR drug targets and corresponding compounds to the pharmaceutical industry for drug development.

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," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions. Forward-looking statements are based on management's beliefs and assumptions and on information available to management only as of the date of this press release. Omeros' actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, risks associated with Omeros' unproven preclinical and clinical development activities, regulatory oversight, commercialization of its products, intellectual property claims and the risks, uncertainties and other factors described under the heading "Risk Factors" in the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2013. 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, even if new information becomes available in the future.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-------------|------------------------------------|-------------|
| | 2013 | 2012 | 2013 | 2012 |
| | (unaudited) | | (unaudited) | |
| Revenue | \$ 196 | \$ 1,417 | \$ 1,431 | \$ 4,439 |
| Operating expenses: | | | | |
| Research and development | 9,420 | 7,764 | 26,111 | 22,568 |
| Selling, general and administrative | 4,210 | 2,736 | 11,934 | 7,270 |
| Litigation settlement | — | 3,953 | — | 3,953 |
| Total operating expenses | 13,630 | 14,453 | 38,045 | 33,791 |
| Loss from operations | (13,434) | (13,036) | (36,614) | (29,352) |
| Investment income | 2 | 14 | 10 | 32 |
| Interest expense | (592) | (413) | (1,768) | (1,360) |
| Other income, (expense) net | 154 | 159 | 421 | (30) |
| Net loss | \$ (13,870) | \$ (13,276) | \$ (37,951) | \$ (30,710) |
| Basic and diluted net loss per common share | \$ (0.46) | \$ (0.51) | \$ (1.36) | \$ (1.30) |
| Weighted-average shares used to compute basic and diluted net loss per common share | 29,844,507 | 25,834,730 | 27,984,133 | 23,578,724 |

OMEROS CORPORATION
CONSOLIDATED BALANCE SHEET DATA
(In thousands)

| | September 30, 2013 | December 31, 2012 |
|--|-----------------------|----------------------|
| Cash and cash equivalents and short-term investments | \$ 8,998 | \$ 22,350 |
| Total assets | 12,014 | 26,575 |
| Total notes payable | 20,395 | 20,103 |
| Total current liabilities | 11,900 | 8,359 |
| Accumulated deficit | (252,528) | (214,577) |
| Total shareholders' equity (deficit) | (23,893) | (6,531) |