OMEROS CORP
Form 10-Q
May 09, 2013
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended March 31, 2013**

**or**

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from _____ to _____**

**Commission file number: 001-34475**

# OMEROS CORPORATION

**(Exact name of registrant as specified in its charter)**

| Washington | 91-1663741 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |
| 201 Elliott Avenue West | |
| Seattle, Washington | 98119 |
| (Address of principal executive offices) | (Zip Code) |

(206) 676-5000

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer x |
| Non-accelerated filer ¨ (Do not check if a smaller reporting company) | Smaller reporting company ¨ |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of May 6, 2013, the number of outstanding shares of the registrant s common stock, par value $0.01 per share, was 25,928,767.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

*This Quarterly Report on Form 10-Q 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, or Exchange Act, which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are forward-looking statements. In some cases you can identify forward-looking statements by terms such as anticipate, believe, could, estimate, expect, goal, intend, may, plan, predict, project, potential, should, will, would, and similar expressions and variations thereof are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:*

- *our ability to submit a New Drug Application, or NDA, and a Marketing Authorization Application, or MAA, for OMS302 during 2013 and to subsequently receive regulatory approval for the commercialization of OMS302 in 2014;*
- *our ability to commence a second Phase 3 clinical trial for OMS103HP during the second half of 2013;*
- *our ability to initiate clinical trials for our MASP-2 and PDE7 programs in 2013;*
- *our ability to raise capital under our at-the-market equity facility with MLV & Co. LLC, or MLV, or to otherwise access the capital markets;*
- *our expectations regarding the clinical benefits of our products;*
- *our expectation that 2014 is the earliest year in which any of our products will be commercially available or generate revenue;*
- *our anticipation that we will rely on contract manufacturers to develop and manufacture our products for commercial sale;*
- *the extent of protection that our patents provide and our pending patent applications may provide, if patents issue from such applications, to our technologies and programs;*
- *our estimate regarding how long our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments;*
- *our involvement in potential claims and legal proceedings, the expected course and costs of existing claims and legal proceedings, and the potential outcomes and effects of both existing and potential claims and legal proceedings on our business, prospects, financial condition and results of operations;*
- *our estimates regarding our future net losses, revenues, research and development expenses and selling, general and administrative expenses.*

*Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part II of this Quarterly Report on Form 10-Q under the heading Risk Factors and in*

*our other filings with the SEC. Given these risks, uncertainties and other factors, actual results or developments anticipated may not be realized or, even if substantially realized, they may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of the filing of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.*

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**OMEROS CORPORATION**

**FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2013**

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**PART I FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**OMEROS CORPORATION**

**CONSOLIDATED BALANCE SHEETS**

**(In thousands, except share and per share data)**

| | March 31, 2013 (unaudited) | December 31, 2012 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 1,281 | $ 1,520 |
| Short-term investments | 12,035 | 20,830 |
| Grant and other receivables | 2,003 | 1,934 |
| Prepaid expenses and other current assets | 494 | 416 |
| Total current assets | 15,813 | 24,700 |
| Property and equipment, net | 1,058 | 1,037 |
| Restricted cash | 679 | 679 |
| Other assets | 143 | 159 |
| Total assets | $ 17,693 | $ 26,575 |
| **Liabilities and shareholders equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,609 | $ 2,632 |
| Accrued expenses | 6,979 | 5,716 |
| Deferred revenue | | 970 |
| Current portion of notes payable, net of discount | 997 | |
| Total current liabilities | 10,585 | 9,318 |
| Notes payable, net of current portion and discount | 19,200 | 20,103 |
| Deferred rent, net of current portion | 3,772 | 3,685 |
| Commitments and contingencies (Note 8) | | |
| Shareholders equity: | | |
| Preferred stock, par value $0.01 per share: | | |
| Authorized shares 20,000,000 at March 31, 2013 (unaudited) and December 31, 2012; | | |
| Issued and outstanding shares none | | |
| Common stock, par value $0.01 per share: | | |
| Authorized shares 150,000,000 at March 31, 2013 (unaudited) and December 31, 2012; | | |
| Issued and outstanding shares 25,910,399 and 25,897,483 at March 31, 2013 (unaudited) and December 31, 2012, respectively | 259 | 259 |
| Additional paid-in capital | 208,943 | 207,787 |
| Accumulated deficit | (225,066) | (214,577) |
| Total shareholders deficit | (15,864) | (6,531) |
| Total liabilities and shareholders equity | $ 17,693 | $ 26,575 |

See notes to consolidated financial statements

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**OMEROS CORPORATION**

**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

**(In thousands, except share and per share data)**

**(unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2013** | **2012** |
| Revenue | $ 1,095 | $ 1,496 |
| Operating expenses: | | |
| Research and development | 7,127 | 7,246 |
| Selling, general and administrative | 3,988 | 2,322 |
| Total operating expenses | 11,115 | 9,568 |
| Loss from operations | (10,020) | (8,072) |
| Investment income | 6 | 12 |
| Interest expense | (587) | (494) |
| Other income (expense), net | 112 | (341) |
| Net loss | $ (10,489) | $ (8,895) |
| Comprehensive loss | $ (10,489) | $ (8,895) |
| Basic and diluted net loss per share | $ (0.40) | $ (0.40) |
| Weighted-average shares used to compute basic and diluted net loss per share | 25,908,153 | 22,434,903 |

See notes to consolidated financial statements

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**OMEROS CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(In thousands)**

**(unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2013** | **2012** |
| **Operating activities** | | |
| Net loss | $ (10,489) | $ (8,895) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 67 | 93 |
| Stock-based compensation expense | 1,093 | 1,131 |
| Non-cash interest expense | 120 | 103 |
| Warrant modification expense | 41 | 511 |
| Changes in operating assets and liabilities: | | |
| Grant and other receivables | (69) | (775) |
| Prepaid expenses and other current and noncurrent assets | (75) | (326) |
| Accounts payable and accrued expenses | 1,227 | 345 |
| Deferred revenue | (970) | (753) |
| Deferred rent, net of current portion | 87 | 3,061 |
| Net cash used in operating activities | (8,968) | (5,505) |
| **Investing activities** | | |
| Purchases of property and equipment | (88) | (72) |
| Purchases of investments | (3,455) | |
| Proceeds from the sale of investments | 12,250 | 19,750 |
| Net cash provided by investing activities | 8,707 | 19,678 |
| **Financing activities** | | |
| Payments on notes payable | | (1,500) |
| Proceeds from issuance of common stock upon exercise of stock options | 22 | 124 |
| Net cash provided by (used in) financing activities | 22 | (1,376) |
| Net (decrease) increase in cash and cash equivalents | (239) | 12,797 |
| Cash and cash equivalents at beginning of period | 1,520 | 4,005 |
| Cash and cash equivalents at end of period | $ 1,281 | $ 16,802 |
| **Supplemental cash flow information** | | |
| Cash paid for interest | $ 313 | $ 402 |

See notes to consolidated financial statements

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**OMEROS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**Note 1 Organization and Significant Accounting Policies**

*Organization*

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced potential products, which we refer to as products, are derived from our proprietary PharmacoSurgery platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical and medical procedures. Our efforts are devoted to conducting research and development of our products, to developing our patent portfolio and to raising equity capital.

*Basis of Presentation*

The accompanying unaudited consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of March 31, 2013 and for the three months ended March 31, 2013 and 2012, includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The consolidated balance sheet at December 31, 2012 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements.

The accompanying unaudited consolidated financial statements and notes to consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto that are included in our Annual Report on Form 10-K for the year ended December 31, 2012.

*Segments*

We operate in one segment. Management uses cash flow as the primary measure to manage our business and does not segment our business for internal reporting or decision-making.

*Principles of Consolidation*

Our consolidated financial statements include the financial position and results of operations of Omeros Corporation, or Omeros, and nura, inc., or nura, our wholly owned subsidiary.

*Use of Estimates*

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from those estimates.

**Note 2 Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of unrestricted common shares and dilutive common share equivalents outstanding for the period, determined using the treasury-stock method and the as if-converted method. The basic and diluted net loss per share amounts for the three months ended March 31, 2013 and 2012 were computed based on the shares of common stock outstanding during the respective periods. Historical outstanding dilutive securities not included in the diluted loss per share calculation are as follows:

| | March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Outstanding options to purchase common stock | 5,356,086 | 4,167,184 |
| Warrants to purchase common stock | 609,016 | 609,016 |
| Total | 5,965,102 | 4,776,200 |

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**Note 3 Cash, Cash Equivalents and Investments**

As of March 31, 2013 and December 31, 2012, all investments are classified as short-term and available-for-sale on the accompanying consolidated balance sheets. We did not own any securities with unrealized loss positions as of March 31, 2013 or December 31, 2012. Investment income consists primarily of interest income.

**Note 4 Fair-Value Measurements**

On a recurring basis, we measure certain financial assets at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The accounting standard establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available. The following summarizes the three levels of inputs required:

Level 1 Observable inputs for identical assets or liabilities, such as quoted prices in active markets;

Level 2 Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3 Unobservable inputs in which little or no market data exists, therefore developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

Our fair-value hierarchy for our financial assets and liabilities measured at fair value on a recurring basis are as follows:

| | March 31, 2013 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| | (In thousands) | | | |
| Assets: | | | | |
| Money-market funds classified as cash equivalents | $ 19 | $ | $ | $ 19 |
| Money-market funds classified as current restricted cash | 193 | | | 193 |
| Money-market funds classified as non-current restricted cash | 679 | | | 679 |
| Money-market funds classified as short-term investments | 12,035 | | | 12,035 |
| Total | $ 12,926 | $ | $ | $ 12,926 |

| | December 31, 2012 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| | (In thousands) | | | |
| Assets: | | | | |
| Money-market funds classified as cash equivalents | $ 21 | $ | $ | $ 21 |
| Money-market funds classified as current restricted cash | 193 | | | 193 |
| Money-market funds classified as non-current restricted cash | 679 | | | 679 |
| Money-market funds classified as short-term investments | 20,830 | | | 20,830 |
| Total | $ 21,723 | $ | $ | $ 21,723 |

Money-market funds classified as current restricted cash are included in prepaid expenses and other current assets on the accompanying consolidated balance sheets. Cash of $1.3 million and $1.5 million is excluded from our fair-value hierarchy disclosure as of March 31, 2013 and December 31, 2012, respectively. There were no unrealized gains and losses associated with our short-term investments as of March 31, 2013 or December 31, 2012.

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**Note 5 Certain Balance Sheet Accounts**

*Accrued Expenses*

Accrued expenses consisted of the following:

| | March 31, 2013 | December, 31 2012 |
|---|---|---|
| | (In thousands) | |
| Deferred rent | $ 1,832 | $ 959 |
| Contract research | 1,368 | 1,447 |
| Clinical trials | 873 | 1,842 |
| Legal | 794 | 323 |
| Employee compensation | 553 | 458 |
| Other accruals | 1,559 | 687 |
| Accrued expenses | $ 6,979 | $ 5,716 |

**Note 6 Notes Payable**

In October 2010, we entered into a loan and security agreement, or, as amended from time to time, the Loan Agreement, with Oxford Finance LLC, or Oxford. Under our Loan Agreement, we had $20.0 million in principal outstanding indebtedness as of March 31, 2013 and December 31, 2012. Interest accrues at an annual fixed rate of 9.25%. The Loan Agreement provides for interest-only payments through December 31, 2013. Beginning on January 1, 2014, payments of principal and interest are payable for 36 months, in arrears. All unpaid principal and accrued and unpaid interest are due and payable on the maturity date, December 1, 2016. As security for our obligations under the Oxford agreement, we granted Oxford a security interest in substantially all of our assets, excluding intellectual property. As of March 31, 2013 unamortized discount and debt issuance costs associated with the debt were $1.3 million and $155,000, respectively.

**Note 7 Revenue**

We have received Small Business Innovative Research grants from the National Institutes of Health, or NIH, which are used to support the research and development of our products. We recorded revenue related to these grants of $125,000 and $160,000 for the three months ended March 31, 2013 and 2012, respectively. As of March 31, 2013, $1.7 million remained available under these grants.

In October 2010, we entered into a platform development funding agreement with Vulcan Inc. and its affiliate, which we refer to collectively as Vulcan, pursuant to which we received $20.0 million for our G protein-coupled receptor, or GPCR, program. Of the funds received from Vulcan, we recorded $10.8 million as a reduction of the cost of the intellectual property assets we purchased from Patobios Limited, or Patobios, $994,000 was recorded in equity for the fair value of warrants issued to Vulcan, and the remaining $8.2 million was recorded as deferred revenue. The deferred revenue balance is being recognized as revenue or as a reduction to the costs of assets purchased in direct proportion to the related GPCR expenses as they are incurred. Also in October 2010, we entered into an agreement with the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or LSDF, under which we received a $5.0 million grant award from LSDF that was paid to reimburse us for expenses we incurred and equipment purchases related to our GPCR program. For the three months ended March 31, 2013 and 2012, we have recorded reductions to the Vulcan deferred revenue balance of $970,000 and $712,000, respectively, which has been recognized as revenue on our accompanying consolidated statements of operations and comprehensive loss. As of March 31, 2013, all amounts pertaining to the Vulcan agreement previously recorded as deferred revenue in the accompanying consolidated balance sheets have been recognized as revenue. We recognized all remaining revenue of $624,000 under the LSDF agreement during the first quarter of 2012.

**Note 8 Commitments and Contingencies**

In December 2006, we entered into a funding agreement with The Stanley Medical Research Institute, or SMRI, to develop a proprietary phosphodiesterase 10, or PDE10, inhibitor product for the treatment of schizophrenia. We hold the exclusive rights to the technology. In connection with the funding agreement with SMRI, beginning the first calendar year after commercial sales of a schizophrenia product, if and when a product is commercialized, we may become obligated to pay royalties based on net income, as defined in the agreement, not to exceed a set multiple of total grant funding received. Based on the amount of grant funding received as of March 31, 2013, the maximum amount of

royalties payable by us is $12.8 million. We have not paid any such royalties through March 31, 2013.

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In February 2009, we entered into a patent assignment agreement with an individual whereby we acquired all intellectual property rights, including patent applications, related to peroxisome proliferators activated receptor gamma, or PPARg, agonists for the treatment and prevention of addictions to substances of abuse, as well as other compulsive behaviors. No payments were made related to the technology acquisition. In February 2011, we amended the patent assignment agreement to include all intellectual property rights, including patent applications, related to dietary supplements that increase PPARg activity. Under the agreement, we will be required to make payments of up to $3.8 million in total, for both PPARg agonists and dietary supplements that increase PPARg activity, to the individual upon achievement of certain development events, such as the initiation of clinical trials and receipt of marketing approval. In addition, we are obligated to pay a low single-digit percentage royalty on any net sales of drug products that are covered by any patents that issue from the acquired patent application.

In March 2010, we entered into a license agreement with Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.), or Daiichi Sankyo, pursuant to which we received an exclusive license to phosphodiesterase 7, or PDE7, inhibitors claimed in certain patents and pending patent applications owned by Daiichi Sankyo for use in the treatment of movement disorders and other specified indications. In February 2011, we amended the agreement to include addiction and compulsive disorders in the field of use. In January 2013, we further amended the agreement to include all other indications except specified dermatologic conditions. Upon execution of the agreement, we paid Daiichi Sankyo of $50,000 that was recognized as research and development expense. Under the amended agreement, we agreed to make milestone payments to Daiichi Sankyo of up to $33.5 million upon the achievement of certain events, such as successful completion of preclinical toxicology studies; dosing of human subjects in Phase 1, 2 and 3 clinical trials; receipt of marketing approval of a PDE7 inhibitor product; and reaching specified sales milestones. However, if only one of the three indications is advanced through each milestone, the total milestone payments would be $23.5 million. In addition, Daiichi Sankyo is entitled to receive from us a low single-digit percentage royalty of any net sales of a PDE7 inhibitor licensed under the agreement by us and/or our sublicensee(s), provided that if the sales are made by a sublicensee, then the amount payable by us to Daiichi Sankyo is capped at an amount equal to a low double-digit percentage of all royalty and specified milestone payments that we receive from the sublicensee.

In April 2010, we entered into an exclusive license agreement with Helion Biotech ApS, or Helion, pursuant to which we received a royalty bearing, worldwide exclusive license in and to all of Helion s intellectual property rights related to mannan-binding lectin-associated serine protease-2, or MASP-2, antibodies, polypeptides and methods in the field of inhibition of mannan-binding lectin-mediated activation of the complement system for the prevention, treatment or diagnosis of any disease or condition. Upon execution of the agreement, we paid Helion $500,000 that was recognized as research and development expense and agreed to make development and sales milestone payments to Helion of up to an additional $6.9 million upon the achievement of certain events, such as the filing of an Investigational New Drug Application, or IND, with the U.S. Food and Drug Administration, or FDA; initiation of Phase 2 and 3 clinical trials; receipt of marketing approval; and reaching specified sales milestones. In addition, Helion is entitled to receive from us a low single-digit percentage royalty of any net sales of a MASP-2 inhibitor product that is covered by the patents licensed by us under the agreement.

In connection with our funding agreements with Vulcan and LSDF discussed in Note 7, we have agreed to pay Vulcan and LSDF tiered percentages of the net proceeds, if any, derived from the GPCR program. The percentage rates of net proceeds payable to Vulcan and LSDF decrease as the cumulative net proceeds reach specified thresholds, and the blended percentage rate payable to Vulcan and LSDF in the aggregate is in the mid-teens with respect to the first approximately $1.5 billion of cumulative net proceeds that we receive from our GPCR program. If we receive cumulative net proceeds in excess of approximately $1.5 billion, the percentage rate payable to Vulcan and LSDF in the aggregate decreases to one percent. Pursuant to the agreement with Vulcan, at our option, we may pay a portion of Vulcan s share of the one percent of net proceeds to a life sciences initiative, or LSI, to be established in accordance with the LSDF agreement. The LSI will be a non-profit, tax-exempt organization with a mission to advance life sciences in the State of Washington.

Net proceeds are defined in the Vulcan and LSDF agreements as (1) all consideration received by us in any form relating directly to the GPCR program, such as from license fees, milestone fees, royalties, product sales, partnerships and a transfer of the GPCR program to a third party, subject to exceptions specified in such agreements, less (2) all expenses and expenditures in excess of $25.0 million incurred by us in connection with the GPCR program such as for research and development, related overhead, milestone and royalty payments, legal expenses, cost of goods sold and product sales deductions. Any consideration that we receive (a) from government entities (subject to specified exceptions), (b) from third parties that have designated such consideration for the purpose of funding research and development expenses and related overhead or (c) in the form of grants, as well as any expenses or expenditures that we incur that are paid for with such consideration, are excluded for purposes of determining net proceeds.

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In November 2010, pursuant to our agreement with Vulcan, we purchased from Patobios intellectual property assets related to an assay technology for use in the GPCR program. We also issued to Vulcan three warrants to purchase our common stock, each with a five-year term and exercisable for 133,333 shares, with exercise prices of $20, $30 and $40 per share, respectively. The exercise price of the warrants may be paid in cash or on a cashless basis in which the number of shares issuable upon exercise of the warrant would be reduced by the number of shares having a fair market value equal to the applicable exercise price. Under our agreement with Vulcan, we granted Vulcan a security interest in our personal property related to the GPCR program, other than intellectual property, which security interest is junior to any existing or future security interests granted in connection with a financing transaction and which will be released automatically after Vulcan receives $25.0 million under the agreement. We also agreed not to grant any liens on intellectual property related to the GPCR program. The term of our agreement with Vulcan is 35 years, provided that the term will automatically extend until the cumulative net proceeds that we receive from the GPCR program are approximately $1.5 billion.

Under our agreement with LSDF, after LSDF receives $25.0 million from us, any remaining amounts that would be payable by us to LSDF pursuant to the agreement will instead be paid to LSI. Our obligations with respect to LSI are limited to creating LSI s charter documents, incorporating LSI, selecting directors and applying for tax-exempt status, all in consultation with LSDF. We have no other obligations, funding or otherwise, to LSI. The term of our agreement with LSDF expires on the six-month anniversary following the last date that we deliver a report related to our incurrence of grant-funded expenses described in the agreement, provided that certain obligations will survive the expiration of the term. The term of our payment obligations to LSDF is the same as that under our agreement with Vulcan.

We currently lease our office and laboratory in The Omeros Building under a lease agreement with BMR-201 Elliott Avenue LLC, or BMR. The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of March 31, 2013, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately $61.7 million and we have received net lease incentives of $4.3 million, which are recorded as deferred rent on our accompanying consolidated balance sheets.

Effective October 26, 2012, Omeros Corporation and Gregory A. Demopulos, M.D., our chairman, chief executive officer, president and interim chief financial officer and treasurer, and Richard J. Klein, our former chief financial officer and treasurer, entered into a settlement agreement and release, or the Settlement Agreement, settling and releasing all of the parties respective claims in the lawsuit described in Part II, Item 1 of our Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission, or SEC, on August 7, 2012. Under an order filed by the U.S. District Court for the Western District of Washington on November 5, 2012, all claims asserted by Omeros, Dr. Demopulos and Mr. Klein were dismissed with prejudice and all of Mr. Klein s claims asserted against Omeros on behalf of the United States Government under the Federal False Claims Act, or the Qui Tam Claims, were dismissed without prejudice to the United States Government. We are currently cooperating with an administrative review by the NIH of two grants that were the subject of Mr. Klein s claims. These grants were made in 2004 and 2007 and involved an aggregate of approximately $1.1 million. Upon completion of its review, the NIH may seek various administrative remedies, including return of all or a portion of the grant proceeds. During the quarter ended March 31, 2013, we recognized as a selling, general and administrative expense and an accrued liability our estimate of the refund that we may elect to pay to the NIH to resolve this matter.

In the Settlement Agreement, each of the parties affirmatively denies any wrongdoing or liability. In addition, the Settlement Agreement bars Mr. Klein and his attorneys from seeking any personal recovery or attorneys fees for the Qui Tam Claims. Under the terms of the Settlement Agreement, in October 2012 we made a one-time payment of $3.94 million to Mr. Klein to release all of his claims, which included a claim for payment of his attorneys fees since 2009 incurred in connection with the lawsuit.

Carolina Casualty Insurance Company, or CCIC, was the carrier for our directors, officers and corporate liability insurance policy in effect at the time Mr. Klein s employment with us was terminated. On February 21, 2012, CCIC filed a complaint for a declaratory judgment against Omeros, Dr. Demopulos and Mr. Klein in the U.S. District Court for the Western District of Washington, seeking a declaration that CCIC owes no duty to indemnify or defend Omeros or Dr. Demopulos against the allegations raised by Mr. Klein. On May 10, 2012, Omeros and Dr. Demopulos filed counterclaims against CCIC alleging that CCIC breached its duty to defend under the insurance policy, acted unreasonably and in bad faith, and unreasonably denied a claim for coverage in violation of Washington law.

CCIC paid approximately $2.0 million of our defense costs associated with Mr. Klein s lawsuit, subject to a reservation of rights, and we paid the remaining portion of the defense costs. Additionally, in November 2012, CCIC reimbursed us $3.95 million for the $3.94 million payment we made to Mr. Klein under the terms of the Settlement Agreement as well as for the $13,000 of related employment taxes that we paid. During the quarter ended December 31, 2012, we recorded $3.95 million as a recovery on settlement. CCIC made this payment without waiving any of its rights and without affecting any of our or our chief executive officer s counterclaims against CCIC, including for failure to defend and bad faith, in the pending lawsuit against CCIC. As of May 9, 2013, CCIC has not amended its complaint to seek such recovery, but may choose to do so in the future. We are defending vigorously CCIC s declaratory judgment action noted above, and we are pursuing our counterclaims. We intend to defend vigorously any attempt by CCIC to recover any amount it paid to us for our defense costs or for

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the $3.95 million reimbursement payment. We do not believe any such recovery attempt by CCIC would succeed. While we can provide no assurances regarding the outcome of the litigation with CCIC, we believe that CCIC is required under the insurance policy to defend and indemnify us in the Klein litigation, including for our defense costs and for the $3.95 million in costs we incurred under the Settlement Agreement. In addition, we believe that CCIC acted unreasonably and in bad faith, and unreasonably denied our claim for coverage in violation of Washington law and are vigorously pursuing these counterclaims. We are seeking to recover from CCIC our damages, including those for violation of Washington State law that are subject to potential trebling. Additionally, if we elect to pay any amounts to the NIH to resolve the ongoing administrative review discussed above, we intend to seek recovery of such amount from CCIC. We can provide no assurance regarding the outcome of our counterclaims against CCIC. While the ultimate financial impact of this action cannot be determined with certainty, based on analysis, we believe that we will not be required to return the amounts paid by CCIC. Therefore, no loss associated with the CCIC actions has been recorded in the financial statements as of March 31, 2013.

**Note 9 Shareholders Equity**

*Warrants*

On March 28, 2012, we extended by one year the expiration dates of warrants to purchase up to an aggregate of 197,478 shares of our common stock at an exercise price of $12.25 per share. As a result of the extension, the expiration date of these warrants was March 29, 2013. On March 28, 2013, we extended the expiration dates of the warrants an additional year to March 29, 2014. We originally issued the warrants on March 29, 2007 to brokers who assisted us in connection with our Series E Preferred Stock financing. Pursuant to accounting guidance regarding equity-based compensation to non-employees, we evaluated the value of the warrants before and after the modification dates to determine the incremental change in their fair value. For the three months ended March 31, 2013 and 2012, we recorded a change in fair value of $41,000 and $511,000, respectively, in other expense.

**Note 10 Stock-Based Compensation**

*Stock Options*

Our 2008 Equity Incentive Plan, or 2008 Plan, provides for the grant of incentive and nonstatutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, directors and consultants and subsidiary corporations employees and consultants. The 2008 Plan also allows any shares returned under our Amended and Restated 1998 Stock Option Plan, or 1998 Plan, as a result of cancellation of options or repurchase of shares issued pursuant to the 1998 Plan, to be issued under the 2008 Plan subject to a maximum limit of 3,084,848 shares. As of March 31, 2013 a total of 365,696 shares have been reserved under the 2008 Plan as a result of the cancellation of options or repurchase of shares under the 1998 Plan. In addition, the 2008 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year, beginning with the 2010 fiscal year, equal to the lesser of:

five percent of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year;

1,785,714 shares; or

such other amount as our board of directors may determine.

On January 1, 2013, in accordance with the 2008 Plan annual increase provisions, the authorized shares in the 2008 Plan increased by 1,294,874 shares. As of March 31, 2013, a total of 5,835,258 shares were reserved for issuance under the 2008 Plan. Options are granted with exercise prices equal to the closing fair market value of the common stock on the date of the grant. The terms of options may not exceed 10 years. Generally, options vest over a four-year period, but may be granted with different vesting terms.

Compensation cost for stock options granted to employees is based on the grant-date fair value and is recognized over the vesting period of the applicable option on a straight-line basis. As stock-based compensation expense is based on options ultimately expected to vest, the expense has been reduced for estimated forfeitures. The fair value of each employee option grant was estimated on the date of grant using the Black-Scholes option- pricing model with the following assumptions during the periods ended:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Estimated weighted-average fair value | N/A | $ 3.21 |
| **Weighted-average assumptions** | | |
| Expected volatility | N/A | 89% |
| Expected term, in years | N/A | 5.72 |
| Risk-free interest rate | N/A | 1.06% |
| Expected dividend yield | N/A | 0% |

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Because no options were granted to employees during the three months ended March 31, 2013, we did not estimate option fair values for this period.

*Stock-Based Compensation Summary*

Stock-based compensation expense includes amortization of stock options granted to employees and non-employees and has been reported in our consolidated statements of operations as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| | (In thousands) | |
| Research and development | $ 581 | $ 568 |
| Selling, general and administrative | 512 | 563 |
| Total | $ 1,093 | $ 1,131 |

Stock option activity and related information is as follows:

| | Options Outstanding | Weighted-Average Exercise Price per Share | Remaining Contractual Life (in years) | Aggregate Intrinsic Value (In thousands) |
|---|---|---|---|---|
| Balance at December 31, 2012 | 5,390,582 | $ 5.18 | | |
| Granted | | | | |
| Exercised | (12,916) | 1.68 | | |
| Forfeited | (21,580) | 7.63 | | |
| Balance at March 31, 2013 | 5,356,086 | $ 5.18 | 7.00 | $ 5,126 |
| Vested and expected to vest at March 31, 2013 | 5,165,630 | $ 5.09 | 6.92 | $ 5,124 |
| Exercisable at March 31, 2013 | 3,363,267 | $ 3.65 | 5.82 | $ 5,114 |

At March 31, 2013, there were 1,992,819 unvested options outstanding that will vest over a weighted-average period of 2.6 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these shares is $9.1 million.

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**ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis should be read in conjunction with the unaudited consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q.*

**Overview**

*Background*

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced potential products, which we refer to as products, are derived from our proprietary PharmacoSurgery platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical and medical procedures. Our PharmacoSurgery platform is based on low-dose combinations of therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to preemptively inhibit inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. We currently have five clinical-stage development programs. In addition, we have a deep and diverse pipeline of preclinical programs as well as a platform capable of unlocking new drug targets. For each of our products and programs, we have retained all manufacturing, marketing and distribution rights.

OMS302, one of our co-lead PharmacoSurgery products, successfully completed a Phase 3 clinical program that evaluated the product in patients undergoing intraocular lens replacement, or ILR, surgery. This clinical program consisted of two trials that enrolled both cataract surgery and refractive lens exchange patients. In both Phase 3 clinical trials, OMS302 demonstrated statistically significant superiority over placebo in maintenance of intraoperative mydriasis (pupil dilation) and reduction of early postoperative pain. We are now preparing to submit an NDA to the FDA during the second quarter of 2013 and an MAA to the European Medicines Agency, or EMA, in mid-2013 to allow us to market and sell OMS302 in the United States and the European Union, respectively. Assuming approval of at least one of these marketing applications within approximately one year of its submission, we expect to begin marketing OMS302 in 2014.

OMS103HP, our other co-lead PharmacoSurgery product, is being evaluated in a Phase 3 clinical program for its safety and ability to reduce pain following arthroscopic partial meniscectomy surgery. In December 2012, we completed a Phase 3 clinical trial in which the pre-specified primary endpoint was the Symptoms Subscale of the KOOS a patient-reported measure that is comprised of questions about knee swelling, clicking, catching and stiffness. In addition, pain measured in the early postoperative period was a pre-specified secondary endpoint. Although the Symptoms Subscale of the KOOS did not reach statistical significance, OMS103HP achieved statistically significant reduction of postoperative pain. We are preparing to conduct a second Phase 3 clinical trial with reduction of early postoperative pain as the primary endpoint. We expect to begin enrolling patients in this second clinical trial in the second half of 2013.

In addition to OMS302 and OMS103HP, we have a pipeline of other product development programs targeting inflammation, coagulopathies and disorders of the central nervous system. We have the following three clinical-stage programs in our pipeline: (1) our PDE10 program lead compound OMS824 for the treatment of cognitive disorders, including schizophrenia and Huntington s disease, is in a Phase 1 clinical program, (2) our PPARg program, in which two Phase 2 clinical trials are being conducted by our collaborators to evaluate a PPARg agonist, alone or in combination with other agents, for treatment of addiction to opioids and to nicotine and (3) our PharmacoSurgery product OMS201 for use during urological surgery, including uroendoscopic procedures, that has completed a Phase 1/Phase 2 clinical trial and which is currently dormant. Our preclinical programs include: (1) our MASP-2 program in which we are developing proprietary MASP-2 antibody therapies to treat disorders associated with complement-activated inflammation (2) our PDE7 program in which we are developing proprietary compounds to treat movement disorders and addiction and compulsive disorders and (3) our Plasmin program in which we are advancing novel antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma as well as for other hyperfibrinolytic states (e.g., liver disease). We currently expect to initiate Phase 1 clinical trials for our MASP-2 and PDE7 programs in 2013.

In our GPCR program, we are working to complete high-throughput surrogate de-orphanization of orphan GPCRs, or the identification of synthetic molecules that bind and functionally interact with the receptors, and to develop products that act at these new potential drug targets. As of May 9, 2013, we have identified and confirmed sets of compounds that interact selectively with, and modulate signaling of, 46 Class A orphan GPCRs.

*Financial Summary*

The majority of our operating expenses to date have been for research and development activities. Research and development expenses consist of costs associated with research activities as well as costs associated with our product development efforts, which include clinical trial and third-party manufacturing services. Internal research and development costs are recognized as incurred. Third-party research and development

costs are expensed at the earlier of when the contracted work has been performed or when upfront and milestone payments are made. Research and development expenses include:

employee and consultant-related expenses, which include salaries and benefits;

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external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, clinical research organizations, or CROs, clinical trial sites, and collaborators or licensors;

facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and depreciation of leasehold improvements and equipment; and

third-party supplier expenses including laboratory and other supplies.

We recognized net losses of $10.5 million and $8.9 million for the three months ended March 31, 2013 and 2012, respectively. These losses have resulted principally from expenses incurred in connection with research and development activities, consisting primarily of clinical trials, preclinical studies and manufacturing services associated with our current products. Compared to 2012, we expect our net losses to increase as we continue to advance our clinical trials, expand our research and development efforts, add personnel for our anticipated growth and prepare for the commercial launch of OMS302, if it is approved. As of March 31, 2013, our accumulated deficit was $225.1 million and total shareholders deficit was $15.9 million.

**Results of Operations**

*Revenue*

Our revenue to date has consisted of grant funding from third parties and revenue recognized in connection with funding received under our agreements with Vulcan and LSDF, which are described in Note 7 to our consolidated financial statements. Other than grant funding, we do not expect to receive any revenue from our products until we receive regulatory approval and commercialize our products or until we potentially enter into collaborative agreements with third parties for the development and commercialization of our products. We do not expect any of our current products to be commercially available before 2014, if at all. We continue to pursue government and private grant funding as well as collaboration funding for our products and research programs.

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| | (In thousands) | |
| Revenue | $ 1,095 | $ 1,496 |

The decrease during the three months ended March 31, 2013 was primarily due to lower total revenue recognized from our GPCR program funding agreements with Vulcan and LSDF. We recognized the remaining revenue in connection with the Vulcan and LSDF agreements during the first quarters of 2013 and 2012, respectively. No further revenue remains to be recognized under these agreements as of March 31, 2013.

*Research and Development Expenses*

Our research and development expenses can be divided into clinical research and development and preclinical research and development activities. The following table illustrates our expenses associated with these activities:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| | (In thousands) | |
| **Direct external expenses:** | | |
| Clinical research and development: | | |
| OMS302 | $ 887 | $ 1,647 |
| OMS103HP | 266 | 991 |
| PDE10 | 374 | 7 |
| Other clinical programs | 11 | 14 |

| | | |
|---|---|---|
| Total clinical research and development | 1,538 | 2,659 |
| Preclinical research and development | 1,600 | 1,405 |
| **Total direct external expenses** | 3,138 | 4,064 |
| Internal, overhead and other expenses | 3,408 | 2,614 |
| Stock-based compensation expense | 581 | 568 |
| **Total research and development expenses** | $ 7,127 | $ 7,246 |

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Direct external clinical research and development expenses consist primarily of external research and development and regulatory expenses incurred pursuant to agreements with third-party manufacturing organizations, CROs, clinical trial sites, collaborators, licensors and consultants. Direct external preclinical research and development expenses consist primarily of our preclinical research activities, laboratory supplies and consulting. Internal, overhead and other expenses consist of personnel costs and other overhead costs such as rent, utilities and depreciation. Our internal resources, employees and infrastructure are not directly tied to any individual research project and are typically deployed across multiple clinical and preclinical projects that we are advancing in parallel.

The decrease in research and development expenses during the three months ended March 31, 2013 was due primarily to lower clinical trials expenses related to the completion of both our OMS302 Phase 3 clinical program in January 2013 and the first OMS103HP Phase 3 clinical trial for meniscectomy in December 2012. These two clinical programs were ongoing during the three months ended March 31, 2012. These decreases were partially offset by higher expenses related to advancing our MASP-2 program toward the clinic, employee costs and non-cash rent expense associated with the amortization of our BMR lease incentives. We expect our research and development expenses to increase in subsequent periods as we continue to advance our OMS103HP and OMS824 products through the clinic and initiate clinical trials for our MASP-2 and PDE7 programs, which we expect to do later in 2013.

At this time, due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our products for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. While we are currently focused on advancing each of our product development programs, our future research and development expenses will depend on the clinical success of each product, as well as on-going assessments of each product s commercial potential. In addition, we cannot forecast with any degree of certainty which products may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

The lengthy process of completing clinical trials and seeking regulatory approval for our products requires the expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations, financial condition and liquidity. We do not expect any of our current products to be commercially available before 2014, if at all. Because of the factors above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

*Selling, General and Administrative Expenses*

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| | (In thousands) | |
| Selling, general and administrative, excluding stock-based compensation expense | $ 3,476 | $ 1,759 |
| Stock-based compensation expense | 512 | 563 |
| Total selling, general and administrative expenses | $ 3,988 | $ 2,322 |

The increase in selling, general and administrative expenses during the three months ended March 31, 2013 was primarily due to legal matters, including expenses in connection with our settled lawsuit with our former chief financial officer and related NIH matter and patent filings and legal fees related to our products, as well as higher expenses associated with the preparation for our planned commercial launch of OMS302 in 2014.

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*Interest Expense*

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| | (In thousands) | |
| Interest expense | $ 587 | $ 494 |

The increase in interest expense during the three months ended March 31, 2013 was due primarily to a higher interest rate and a higher average balance on our Oxford notes during the 2013 period.

*Other Income (Expense), Net*

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| | (In thousands) | |
| Other income (expense), net | $ 112 | $ (341) |

Other income (expense) principally includes rental income and costs associated with warrant modifications. Warrant modification expenses decreased from $511,000 in 2012 to $41,000 in 2013.

**Liquidity and Capital Resources**

As of March 31, 2013, we had $13.3 million in cash, cash equivalents and short-term investments. Our cash, cash equivalents and short-term investment balances are held principally in interest-bearing instruments, including money-market accounts. Cash in excess of immediate requirements is invested in accordance with established guidelines to preserve principal and maintain liquidity. We believe that our existing cash, cash equivalents and short-term investments and capital that we may be able to raise under our agreement with MLV, should we decide to do so, will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months. We may also consider other funding alternatives such as corporate partnerships, debt and equity financing.

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| | (In thousands) | |
| **Selected cash flow data** | | |
| Cash provided by (used in): | | |
| Operating activities | $ (8,968) | $ (5,505) |
| Investing activities | 8,707 | 19,678 |
| Financing activities | 22 | (1,376) |

*Operating Activities.* Expenditures related to operating activities in these periods were primarily for research and development and selling, general and administrative expenses in support of our operations. Net cash used in operating activities increased for the three months ended March 31, 2013 primarily due to higher expenses related to advancing our MASP-2 program toward the clinic, increased marketing expenses tied to the planned commercial launch of OMS302 in 2014 and higher legal and employee costs. In addition, cash used in operating activities was reduced in the 2012 period by a $3.0 million cash lease incentive payment that we received from BMR. The increases in 2013 were partially offset by lower clinical trial expenses related to the completion of Phase 3 clinical trials for our OMS302 and OMS103HP programs in January 2013 and December 2012, respectively.

*Investing Activities.* Investing activities, other than the purchases and sales of short-term investments, consist primarily of purchases of property and equipment. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and receipts from the sale of short-term investments, thus causing a shift between our cash and cash equivalents and short-term investment balances. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider these cash flows to be important to the

understanding of our liquidity and capital resources.

*Financing Activities.* During the 2012 period, cash used in financing activities primarily related to principal payments on our Oxford notes. In December 2012, we amended the Oxford notes to provide for interest-only payments through December 31, 2013, resulting in decreased cash used in financing activities during the 2013 period.

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*Funding Requirements*

Because of the numerous risks and uncertainties associated with the development and commercialization of our products, and to the extent that we may or may not enter into collaborations with third parties to participate in development and commercialization, we are unable to estimate the amounts of increased capital requirements and operating expenditures required in the future. Our future operating and capital requirements will depend on many factors, including:

- the progress and results of our preclinical and clinical programs;
- costs related to manufacturing services;
- whether the hiring of a number of new employees to support our continued growth will occur at salary levels consistent with our estimates;
- the terms and timing of payments of any collaborative or licensing agreements that we have or may establish;
- the cost, timing and outcomes of the regulatory processes for our products;
- the costs of commercialization activities, including product manufacturing, marketing, sales and distribution;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to these types of transactions;
- whether we receive grant funding for our programs;
- the extent to which we raise capital by selling our stock through our at-the-market equity facility with MLV, under which MLV is required to use its commercially reasonable efforts to sell our stock in accordance with our instructions;
- the extent to which we otherwise access the capital markets;
- the outcomes of our existing claims and legal proceedings; and
- the amount of revenue we generate from the sale of our products, which revenue we do not expect until at least 2014.

We expect our continued operating losses to result in an increase in the total amount of cash used in operations over the next several years. To meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we do not raise additional capital through equity or debt financings and/or one or more

corporate partnerships, we may be required to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts. We currently do not have any commitments for future external equity or debt funding other than our committed equity line financing facility described below that we do not expect to use before it expires on June 1, 2013. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all, and any future equity funding will dilute the ownership of our equity investors.

*MLV At-the-Market Agreement*

In December 2012, we entered into an at-the-market issuance sales agreement, or the Sales Agreement, with MLV pursuant to which we may direct MLV to sell shares of our common stock having an aggregate offering price of up to $60.0 million directly on The NASDAQ Global Market or through or to a market maker other than on an exchange. With our prior written consent, sales may also be made in negotiated transactions and/or any other method permitted by law. MLV will receive a 2.0% commission from the gross proceeds of any sales. Subject to the terms and conditions of the Sales Agreement, MLV will use its commercially reasonable efforts to sell the shares of our common stock from time to time, based upon our instructions (including any price, time or size limits or other parameters or conditions that we may impose). We are not obligated to make any sales of common stock under the Sales Agreement and no assurance can be given that we will sell any shares under the Sales Agreement, or, if we do, as to the price or amount of shares that we will sell, or the dates on which any such sales will take place. The Sales Agreement may be terminated by either party at any time upon 10 days notice to the other party, or by MLV at any time in certain circumstances, including the occurrence of a material adverse effect to Omeros. In addition, the Sales Agreement will automatically terminate upon the sale of all common stock subject to the Sales Agreement.

*Azimuth Committed Equity Line Financing Facility*

In May 2011, we entered into a committed equity line financing facility with Azimuth Opportunity, Ltd., or Azimuth, pursuant to which we are permitted to sell up to $40.0 million of our shares of common stock over a 24-month term. This facility replaced a prior committed equity line financing facility, which we entered into with Azimuth on July 28, 2010 but had not accessed. Under the 2011 agreement with Azimuth, we may, from time to time over the 24-month term and in our sole discretion, present Azimuth with draw down notices requiring Azimuth to purchase a specified dollar amount of shares of our common stock, based on the volume-weighted average price per share on each of 10 consecutive trading days, or the draw down period, with the total dollar amount of each draw down subject to certain agreed-upon limitations based on the market price of our common stock at the time of the draw

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down. The purchase price for these shares equals the daily volume-weighted average price of our common stock on each date during the draw down period on which shares are purchased, less a discount ranging from 3.00% to 6.00%, based on a minimum price that we specify. We are allowed to present Azimuth with up to 24 draw down notices during the 24-month term, with only one such draw down notice allowed per draw down period and a minimum of five trading days required between each draw down period. We may not issue more than 4,427,562 shares in connection with the committed equity line financing facility, although this limitation does not apply if the average purchase price of all shares issued to Azimuth, taking into account all discounts, equals or exceeds $5.02 per share, which amount is subject to adjustment in certain circumstances specified in the facility. We have not drawn down funds under this facility to date and it will expire on June 1, 2013 unless we and Azimuth mutually agree to extend it. Because the facility will expire on June 1, 2013, taking into account its limitations described above, we believe that the amount of committed proceeds that we could raise before June 1, 2013 would be significantly less than $40.0 million. We are unable to estimate the actual amount as it depends on the price of our stock at the time we use the facility.

In connection with this facility, we entered into a placement agent agreement with Reedland Capital Partners, an Institutional Division of Financial West Group, member FINRA/SIPC, or FWG/Reedland. We have agreed to pay FWG/Reedland, upon each sale of our common stock to Azimuth under the facility, a fee equal to 0.5% of the aggregate dollar amount of common stock purchased by Azimuth.

*Oxford Loan and Security Agreement*

In October 2010, we entered into the Loan Agreement with Oxford pursuant to which Oxford agreed to lend us up to $20.0 million in two tranches of $10.0 million each. We borrowed the first tranche in October 2010, or Tranche 1, and the second tranche in March 2011, or Tranche 2. In December 2012, we entered into an amendment to the Loan Agreement pursuant to which we borrowed an additional $7.2 million, or Tranche 3, and amended the repayment terms of the existing outstanding indebtedness under Tranche 1 and Tranche 2. We had $20.0 million in principal outstanding indebtedness under the Loan Agreement as of March 31, 2013. Interest accrues at an annual fixed rate of 9.25%. The Loan Agreement provides for interest-only payments through December 31, 2013. In connection with the Loan Agreement, we agreed to pay Oxford a final payment fee equal to 7.0% of the borrowed $20.0 million, or $1.4 million, which we recorded as a discount on the outstanding debt. The final payment fee will be due upon the last payment date of the amounts we borrowed, whether upon maturity on December 1, 2016, or on the date of any prepayment of such amounts or in the event of acceleration upon a default. We also capitalized in other assets $168,000 in debt issuance costs that we incurred. Both of these amounts are being amortized to interest expense using the effective-interest method over the amended repayment term.

We may prepay the outstanding principal balance under the Loan Agreement in its entirety, plus accrued and unpaid interest, at any time upon delivery of prior notice to Oxford and the payment of a prepayment fee equal to 1.0% of the then-outstanding principal amount, which prepayment fee would be waived if we refinance the indebtedness with Oxford. As security for its obligations under the Loan Agreement, we granted Oxford a security interest in substantially all of our assets, excluding intellectual property. The Loan Agreement contains customary affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, or repurchase stock, in each case subject to customary exceptions for a loan agreement of this size and type. The Loan Agreement contains no cash covenant.

The Loan Agreement includes customary events of default that include, among other things, non-payment, inaccuracy of representations and warranties, covenant breach, occurrence of a material adverse effect, or MAE, cross default to material indebtedness, bankruptcy or insolvency, material judgment defaults, and a change of control. The occurrence of an event of default could result in the acceleration of our indebtedness to Oxford. Under certain circumstances, a default interest rate will apply on all obligations during the existence of an event of default under the Loan Agreement at a per annum rate equal to 5.0% above the otherwise applicable interest rate.

MAE is defined in the Loan Agreement as a material adverse effect upon (i) the business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our inability to repay any portion of the loans in accordance with the terms of the Loan Agreement, (ii) the validity, perfection, value or priority of Oxford s security interest in the collateral, (iii) the enforceability of any material provision of the Loan Agreement or related agreements or (iv) the ability of Oxford to enforce its rights and remedies under the Loan Agreement or related agreements. We considered the MAE definition and believe that the MAE clause has not been triggered as of March 31, 2013.

*Carolina Casualty Insurance Company Litigation*

Under the terms of the Settlement Agreement discussed in Part II, Item 1 Legal Proceedings to this Quarterly Report on Form 10-Q, in the fourth quarter of 2012 we made a one-time payment of $3.94 million to Mr. Klein to release all of his claims, which included a claim for payment of his attorneys fees since 2009 incurred in connection with the lawsuit. As of December 31, 2012, we

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recorded $3.95 million as litigation settlement on our statements of operations and comprehensive loss. As also described in Part II, Item 1 Legal Proceedings to this Quarterly Report on Form 10-Q, we are currently engaged in litigation with CCIC, which was the carrier for our directors, officers and corporate liability insurance policy in effect at the time Mr. Klein s employment with us was terminated.

CCIC paid approximately $2.0 million of our defense costs associated with Mr. Klein s lawsuit, subject to a reservation of rights, and we paid the remaining portion of the defense costs. Additionally, in November 2012, CCIC reimbursed us $3.95 million for the $3.94 million payment we made to Mr. Klein under the terms of the Settlement Agreement as well as for the $13,000 of related employment taxes that we paid. During the quarter ended December 31, 2012, we recorded $3.95 million as a recovery on settlement on the accompanying statements of operations and comprehensive loss. CCIC made this payment without waiving any of its rights and without affecting any of our or our chief executive officer s counterclaims against CCIC, including for failure to defend and bad faith, in the pending lawsuit against CCIC. As of May 9, 2013, CCIC has not amended its complaint to seek recovery of defense costs or the settlement payment, but may choose to do so in the future.

We are defending vigorously CCIC s declaratory judgment action noted above, and we are pursuing our counterclaims. We intend to defend vigorously any attempt by CCIC to recover any amount it paid to us for our defense costs or for the $3.95 million reimbursement payment. We do not believe any such recovery attempt by CCIC would succeed. While we can provide no assurances regarding the outcome of the litigation with CCIC, we believe that CCIC is required under the insurance policy to defend and indemnify us in the Klein litigation, including for our defense costs and for the $3.95 million in costs we incurred under the Settlement Agreement. In addition, we believe that CCIC acted unreasonably and in bad faith, and unreasonably denied our claim for coverage in violation of Washington law and are vigorously pursuing these counterclaims. We are seeking to recover from CCIC our damages, including those for violation of Washington State law that are subject to potential trebling. We can provide no assurance regarding the outcome of our counterclaims against CCIC. The ultimate financial impact of this action is not yet determinable. If we are required to repay to CCIC the settlement funds or any part of our defense costs and fees borne by CCIC, or both, our financial position may be materially negatively affected.

**Contractual Obligations and Commitments**

We currently lease our office and laboratory space in The Omeros Building under a lease agreement with BMR. The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of March 31, 2013, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately $61.7 million and we have received net lease incentives of $4.3 million, which were recorded as deferred rent on our accompanying consolidated balance sheet.

We may also be required to make certain royalty and milestone payments that we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur. Please see Note 8 to our consolidated financial statements included in this Quarterly Report on Form 10-Q for a description of the agreements that include these royalty and milestone payment obligations.

**Critical Accounting Policies and Significant Judgments and Estimates**

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from those estimates. An accounting policy is considered critical if it is important to a company s financial condition and results of operations, and if it requires the exercise of significant judgment and the use of estimates on the part of management in its application. Although we believe that our judgments and estimates are appropriate, actual results may differ materially from our estimates.

For a more detailed listing of our critical accounting estimates, refer to our 2012 Form 10-K.

**Off-Balance Sheet Arrangements**

We have not engaged in any off-balance sheet arrangements.

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**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk is primarily confined to our investment securities and notes payable. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities. As of March 31, 2013, we had cash, cash equivalents and short-term investments of $13.3 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These securities in our investment portfolio are not leveraged and are classified as available-for-sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates and with our current portfolio of short term investments. We are not exposed to potential loss due to changes in interest rates.

**ITEM 4. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive and financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of March 31, 2013. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2013, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

Effective October 26, 2012, Omeros Corporation and Gregory A. Demopulos, M.D., our chairman, chief executive officer, president and interim chief financial officer and treasurer, and Richard J. Klein, our former chief financial officer and treasurer, entered into a settlement agreement and release, or the Settlement Agreement, settling and releasing all of the parties respective claims in the lawsuit captioned *United States of America, ex. rel. Richard J. Klein v. Omeros Corporation and Gregory Demopulos*, No. C09-1342 JCC. This lawsuit is described in Part II, Item 1 of our Quarterly Report on Form 10-Q filed with the SEC on August 7, 2012. Under an order filed by the U.S. District Court for the Western District of Washington on November 5, 2012, all claims asserted by Omeros, Dr. Demopulos and Mr. Klein were dismissed with prejudice and all of Mr. Klein s claims asserted against Omeros on behalf of the United States Government under the Federal False Claims Act, or the Qui Tam Claims, were dismissed without prejudice to the United States Government, which was not a party to the proceeding. We are currently cooperating with an administrative review by the National Institutes of Health, or NIH, of two grants that were the subject of the Qui Tam Claims. These grants were made in 2004 and 2007 and involved an aggregate of approximately $1.1 million. Upon completion of its review, the NIH may seek various administrative remedies, including return of all or a portion of the grant proceeds.

CCIC was the carrier for our directors, officers and corporate liability insurance policy in effect at the time Mr. Klein s employment with us was terminated. CCIC paid approximately $2.0 million of our defense costs associated with Mr. Klein s lawsuit, subject to a reservation of rights, and we paid the remaining portion of the defense costs. On February 21, 2012, CCIC filed a complaint for a declaratory judgment against Omeros, Dr. Demopulos and Mr. Klein in the U.S. District Court for the Western District of Washington, seeking a declaration that CCIC owes no duty to indemnify or defend Omeros or Dr. Demopulos against the allegations raised by Mr. Klein. On May 10, 2012, Omeros and Dr. Demopulos filed counterclaims against CCIC alleging that CCIC breached its duty to defend under the insurance policy, acted unreasonably and in bad faith, and unreasonably denied a claim for coverage in violation of Washington law. On November 19, 2012 CCIC reimbursed us $3.95 million for the $3.94 million payment we made to Mr. Klein under the terms of the Settlement Agreement as well as for the $13,000 of related employment taxes that we paid. CCIC made this payment without waiving any of its rights and without affecting any of our or our chief executive officer s counterclaims against CCIC, including for failure to defend and bad faith, in the pending lawsuit with CCIC. As of May 9, 2013, CCIC has not amended its complaint to seek such recovery, but may choose to do so in the future.

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**ITEM 1A. RISK FACTORS**

*Our business, prospects, financial condition or operating results could be materially adversely affected by any of the risks and uncertainties described below, as well as other risks not currently known to us or that we currently deem immaterial. You should carefully consider these risks before making an investment decision. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2012.*

**Risks Related to Our Products, Programs and Operations**

**We are focusing a significant portion of our activities and resources on OMS302 and our success may largely depend on our ability to obtain regulatory approval and to successfully commercialize this product.**

We are a biopharmaceutical company with no products approved for commercial sale and we have not generated any revenue from product sales. We have incurred, and expect to continue to incur, significant costs relating to the development and commercialization of our co-lead products, OMS302 for use during ILR procedures and OMS103HP for use during arthroscopic partial meniscectomy surgery. We intend to focus a significant portion of our activities and resources on seeking regulatory approval for, and subsequently commercializing, OMS302, and we believe a substantial portion of the value of our company relates to our ability to obtain marketing approval for, and to successfully commercialize, this product.

We are now preparing to submit an NDA and an MAA for OMS302. Before either the FDA or EMA will begin its substantive review of the applicable marketing application, it will conduct a preliminary review to determine whether our submission includes all of the information that such agency believes necessary to evaluate OMS302 for possible marketing approval. The regulatory process is subject to substantial agency discretion and risks, including those described later in these risk factors. If one or both of these agencies refuses to accept our application(s), we may be required to revise our application(s) to include additional information about OMS302, which may require us to conduct additional clinical trials or preclinical studies that may significantly delay our ability to market and generate revenue from the sale of OMS302. Even if our NDA and MAA are accepted for review, either agency may decide not to approve our application, requiring us to obtain additional data regarding OMS302 and to resubmit our marketing application(s), further delaying our ability to market and generate revenue from the sale of OMS302.

Even if we receive regulatory approval for OMS302, our ability to successfully commercialize this product will be subject to numerous uncertainties and risks, including those described later in these risk factors. If there are any negative decisions or delays in the regulatory process or if the anticipated or actual timing and plan for commercializing OMS302, or, ultimately, the market acceptance of OMS302 do not meet our, your, analysts or others expectations, the market price of our common stock could decline significantly.

**Our success may also largely depend on the success of OMS103HP, and we cannot be certain that it will receive regulatory approval or be successfully commercialized.**

We are conducting a Phase 3 clinical program evaluating OMS103HP in patients undergoing arthroscopic partial meniscectomy surgery and plan to begin enrolling patients in a second Phase 3 clinical trial in 2013. While OMS103HP demonstrated a drug effect in the first Phase 3 clinical trial by reducing early postoperative pain, we can provide no assurance that in subsequent trials OMS103HP will meet the primary endpoint of early postoperative pain reduction following arthroscopic partial meniscectomy or that more than two additional trials, which we currently expect to conduct, will be required by regulatory authorities. Also, we can provide no assurances that we will have sufficient resources to conduct any subsequent clinical trials that we or regulatory authorities may deem necessary. If the data from any subsequent trials are negative or if we are required to conduct more than two additional clinical trials, we may be unable to seek, or be significantly delayed in seeking, marketing approval of OMS103HP, which could cause the market price of our common stock to decline significantly.

**We are subject to extensive government regulation, including the requirement of approval before our products may be marketed.**

Both before and after approval of our products, we, our products, and our suppliers and contract manufacturers are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution, and import and export. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: warning letters; unanticipated expenditures; delays in approval or refusal to approve a product; product recall or seizure; interruption of manufacturing or clinical trials; operating restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties. We, the FDA or an independent Institutional Review Board or Ethics Committee may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are being

exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials.

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Our products cannot be marketed in the United States without FDA approval, and can only be marketed for the indications for which they may be approved. The FDA has not approved any of our products for sale in the United States. All of our products are in development, and will have to be approved by the FDA before they can be marketed in the United States. Obtaining FDA approval requires substantial time, effort, and financial resources, and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on a timely basis, if at all.

The FDA may decide that our data are insufficient for approval of our products and require additional preclinical, clinical or other studies. As we develop our products, we periodically discuss with the FDA clinical, regulatory and manufacturing matters, and our views may, at times, differ from those of the FDA. For example, the FDA regulates our products that consist of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product s effectiveness. The FDA has questioned the means by which we intend to demonstrate such contribution and whether available data and information demonstrate contribution for each active ingredient in OMS103HP. If we are unable to resolve these questions, we may be required to provide additional information, which may include the results of additional preclinical studies or clinical trials.

If we are required to conduct additional clinical trials or other testing of our products beyond those that we currently contemplate for regulatory approval, if we are unable to successfully complete our clinical trials or other testing, or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may be delayed in obtaining marketing approval for our products, or may never be able to obtain marketing approval.

Even if regulatory approval of a product is obtained, such approval may be subject to significant limitations on the indicated uses for which that product may be marketed, conditions of use, and/or significant post approval obligations, including additional clinical trials. These regulatory requirements may, among other things, limit the size of the market for the product. Even after approval, discovery of previously unknown problems with a product, manufacturer, or facility, such as previously undiscovered side effects, may result in restrictions on any product, manufacturer, or facility, including, among other things, a possible withdrawal of approval of the product.

**Our existing and future products, including our co-lead products OMS302 and OMS103HP, may never achieve market acceptance even if we obtain regulatory approvals.**

Even if we receive regulatory approvals for the commercial sale of one or more of our existing or future products, including OMS302 and OMS103HP, the commercial success of these products will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community. If our products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the effectiveness of our marketing and distribution strategy to, among others, hospitals, surgery centers, physicians and/or pharmacists;
- prevalence of the condition for which the product is approved or frequency of the related surgical procedure;
- acceptance by physicians of each product as a safe and effective treatment;
- perceived advantages over alternative treatments;

relative convenience and ease of administration;

the availability of adequate reimbursement by third parties;

the frequency and severity of adverse side effects; and

publicity concerning our products or competing products and treatments.

Further, the number of operations in which our PharmacoSurgery products, if approved, would be used may be significantly less than the total number of such operations performed. If our products do not become widely accepted by physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable, and if we are unable to increase market penetration of our products, our growth prospects would be significantly harmed.

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**If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate product revenue.**

Omeros has never sold, marketed or distributed any biopharmaceutical product. Developing an internal sales force is expensive and time-consuming and commonly is commenced 18 months in advance of product launch. Any delay in developing an internal sales force could impact the timing of any product launch. If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any approved products that we develop ourselves. Factors that may inhibit our efforts to commercialize any approved products without collaboration partners include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to sell our product(s) to adequate numbers of hospitals, surgery centers, physicians and/or pharmacists to purchase, use or prescribe any approved products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unsuccessful in building a sales and marketing infrastructure or unable to partner with one or more third parties to perform sales and marketing services for our products, we will have difficulty commercializing our products, which would adversely affect our business and financial condition.

**We have a history of operating losses, and we may not achieve or maintain profitability.**

We have not been profitable and have generated substantial operating losses since we were incorporated in June 1994. We had net losses of approximately $10.5 million and $8.9 million for the three months ended March 31, 2013 and 2012, respectively. As of March 31, 2013, we had an accumulated deficit of approximately $225.1 million. We do not anticipate generating revenue from the sale of our products until 2014 at the earliest and expect to incur additional losses for at least the next several years and cannot be certain that we will ever achieve profitability. As a result, our business is subject to all of the risks inherent in the development of a new business enterprise, such as the risks that we may be unable to obtain additional capital needed to support the preclinical and clinical expenses of development and commercialization of our products, to develop a market for our products, to successfully transition from a company with a research and development focus to a company capable of commercializing products and to attract and retain qualified management as well as technical and scientific staff.

**If we are unable to raise additional capital when needed or on acceptable terms, we may be unable to complete the development and commercialization of OMS302, OMS103HP or our other products, or continue our other preclinical development programs.**

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- submit the NDA and MAA for OMS302 to the FDA and EMA, respectively, and prepare for the product s potential commercialization;
- complete the Phase 3 clinical program of OMS103HP for use in arthroscopic partial meniscectomy surgery;
- continue the clinical development of OMS824;

continue our development efforts in our GPCR program to advance this program for potential partnering or for internal development of products targeting GPCRs;

scale-up and produce clinical and commercial supplies of products, and conduct clinical studies for our products, including for our PDE7, MASP-2 and Plasmin programs;

continue research and development in all of our programs;

make principal and interest payments when due under our debt facility with Oxford;

initiate and conduct clinical trials for other products;

make milestone payments to our collaborators; and

launch and commercialize any products for which we receive regulatory approval.

If we do not raise additional capital, we may be unable to commercialize OMS302, if it is approved, or complete all of the clinical trials in our Phase 3 clinical program for OMS103HP, which would prevent us from generating sales revenue for one or both of those products. Also, our clinical trials may be delayed or we may need to conduct additional trials for many of the reasons discussed in these Risk Factors, which would increase our development expenses and may require us to raise additional capital to complete their clinical development and commercialization and to decrease spending on our other development programs.

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Furthermore, we may need to raise additional capital to continue the clinical development of OMS824 and to advance one or more of our preclinical programs into clinical development. If we are unable to raise sufficient capital to commercialize OMS302 or complete the clinical development of OMS103HP or advance the development of one or more of our other programs, our business and prospects could be harmed and our stock price could decline significantly.

**If our clinical trials are delayed, we may be unable to develop our products on a timely basis, which will increase our development costs and delay the potential commercialization of our products and the subsequent receipt of revenue from sales, if any.**

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory agencies, Institutional Review Boards or Ethics Committees, or us to delay our clinical trials or suspend or delay the analysis of the data from those trials. Clinical trials can be delayed for a variety of reasons, including:

- discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays or the inability to obtain required approvals from Institutional Review Boards, Ethics Committees or other responsible entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- lower than anticipated retention rates of patients in clinical trials;
- the need to repeat or conduct additional clinical trials as a result of problems such as inconclusive or negative results, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol or an unacceptable study design;
- an insufficient supply of product materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product materials for FDA and foreign regulatory approval;
- an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials; or
- the placement of a trial on a clinical hold.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities, or Institutional Review Boards or Ethics Committees due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues or any determination that a trial presents unacceptable health risks; or

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our contract research organizations, CROs, and other third parties.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards or Ethics Committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial. If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to file for regulatory approval or conduct additional clinical trials on the schedule we currently anticipate. Any delays in completing our clinical trials may increase our development costs, would slow down our product development and regulatory submission process, could delay our receipt of product revenue and could make it difficult to raise additional capital. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products and may harm our business.

**We rely on third parties to conduct portions of our preclinical research and clinical trials. If these third parties do not perform as contractually required or otherwise expected, or if we fail to adequately supervise or monitor these parties, we may not be able to obtain regulatory approval for or commercialize our products.**

We rely on third parties, such as CROs and research institutions, to conduct a portion of our preclinical research. We also rely on third parties, such as medical institutions, clinical investigators and CROs, to assist us in conducting our clinical trials. Nonetheless, we are responsible for confirming that our preclinical research and clinical trials are conducted in accordance with applicable regulations, the relevant trial protocol and within the context of approvals by an Institutional Review Board or Ethics Committee, and we may not always be successful in ensuring such compliance. Our reliance on these third parties does not relieve us of responsibility

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for ensuring compliance with FDA and other regulations and standards for conducting, monitoring, recording and reporting the results of preclinical research and clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical and clinical development processes may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our products.

**We have no capacity to manufacture clinical or commercial supplies of our products and intend to rely solely on third parties to manufacture clinical and commercial supplies of all of our products.**

We do not intend to manufacture our products for our clinical trials or on a commercial scale and intend to rely on third parties to do so. With the exception of our agreement with Hospira Worldwide, Inc. for the commercial supply of liquid OMS103HP, we have not yet entered into any agreement for the commercial supply of any of our products, including OMS302, and can provide no assurance that we will be able to do so on commercially reasonable terms, if at all. Any significant delays in the manufacture of clinical or commercial supplies of our products could materially harm our business and prospects.

**If the contract manufacturers that we rely on experience difficulties with manufacturing our products or fail FDA inspections, our clinical trials, regulatory submissions and ability to commercialize our products and generate revenue may be significantly delayed.**

Contract manufacturers that we select to manufacture our products for clinical testing or for commercial use may encounter difficulties with the small- and large-scale formulation and manufacturing processes required for such manufacture. These difficulties could result in delays in clinical trials, regulatory submissions, or commercialization of our products. Once a product is approved and being marketed, these difficulties could also result in the later recall or withdrawal of the product from the market or failure to have adequate supplies to meet market demand. Even if we are able to establish additional or replacement manufacturers, identifying these sources and entering into definitive supply agreements and obtaining regulatory approvals may require a substantial amount of time and cost and such supply arrangements may not be available on commercially reasonable terms, if at all.

In addition, we and our contract manufacturers must comply with current good manufacturing practice requirements strictly enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. We or our contract manufacturers may be unable to comply with current good manufacturing practice requirements or with other FDA, state, local and foreign regulatory requirements. Although we have obligations to review their compliance, we have little control over our contract manufacturers compliance with these regulations and standards, or with their quality control and quality assurance procedures. Large-scale manufacturing processes that have been developed for our products will require validation studies, which the FDA must review and approve. Failure to comply with these requirements by our contract manufacturers could result in the initiation of enforcement actions by the FDA and other regulatory authorities, as well as sanctions being imposed on us, including fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product supplied by contract manufacturers is compromised due to their failure to adhere to applicable laws or for other reasons, we may not be able to obtain or maintain regulatory approval for or successfully commercialize one or more of our products, which would harm our business and prospects significantly.

If one or more of our contract manufacturers were to encounter any of these difficulties or otherwise fail to comply with its contractual obligations, our ability to provide products to patients in our clinical trials or on a commercial scale would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending on the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must first approve these manufacturers facilities and processes, which could require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our products.

**Ingredients necessary to manufacture our PharmacoSurgery products may not be available on commercially reasonable terms, if at all, which may delay the development and commercialization of our products.**

We must purchase from third-party suppliers the ingredients necessary for our contract manufacturers to produce our PharmacoSurgery products for our clinical trials and, if approved, for commercial distribution. Suppliers may not sell these ingredients to us at the time we need them or on commercially reasonable terms, if at all. Although we intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of ingredients for our PharmacoSurgery products, we have not yet entered into and we may be unable to secure any such supply agreements or guarantees. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients in a timely manner or in the minimum guaranteed quantities. If we are unable to obtain and then supply these

ingredients to our contract manufacturers for our clinical trials, potential regulatory approval of our products would be delayed, significantly impacting our ability to develop our products, which would materially affect our ability to generate revenue from the sale of our products.

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**We may need licenses for active ingredients from third parties so that we can develop and commercialize some products from some of our current preclinical programs, which could increase our development costs and delay our ability to commercialize products.**

Should we decide to use active ingredients in any of our products that are proprietary to one or more third parties, we would need to obtain licenses to those active ingredients from those third parties. For example, we intend to use proprietary active ingredients that we have exclusively licensed from Daiichi Sankyo Co., Ltd. for our PDE7 program. If we are unable to access rights to these active ingredients prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate products from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these products. If we are unable to access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, we may not be able to commercialize products from these programs.

**Our agreements with Vulcan and LSDF include terms that may reduce the purchase price that a third party would be willing to pay for the GPCR program or for us in a change of control, should we elect to proceed with either of such transactions.**

Under our GPCR funding agreement with Vulcan, if we decide to sell or assign all or substantially all of the assets in our GPCR program prior to the time that Vulcan has received $60.0 million from us under our agreement, Vulcan may require that the purchaser assume all of our rights and obligations pursuant to the agreement, including our obligation to pay tiered percentages of any net proceeds that we receive from the GPCR program. The term of the Vulcan agreement is at least 35 years. If, at our option, we elect to assign the LSDF agreement in connection with the sale of the GPCR program, a potential purchaser would also have to assume similar payment obligations to LSDF. Potential purchasers of our GPCR program may be less inclined to purchase the program because of these obligations. Further, even if they are willing to assume our rights and obligations, they may be unwilling to pay as much for our GPCR program as they would be without such requirement. In addition, if a transaction results in a change of control of Omeros, the acquiring party will be required to assume our rights and obligations under the Vulcan and LSDF agreements. As a result of these provisions, a party that wants to acquire us through a change of control may be less inclined to do so or not be willing to pay as much.

**We have granted Vulcan a lien on all of our GPCR assets, excluding intellectual property, that provides Vulcan a right, senior to our shareholders, to receive proceeds generated from a liquidation of our GPCR assets as well as potentially limiting our operating and financial flexibility.**

We have granted Vulcan a lien on all of our GPCR assets, excluding intellectual property, to secure our obligations under our agreement with Vulcan. This lien is, and will continue to be, junior to security interests we grant to third parties, such as Oxford, in connection with indebtedness for borrowed money. The lien will automatically be released once we have paid Vulcan or its affiliate $25.0 million out of net proceeds received from the GPCR program. If we default under our agreement with Vulcan, in certain circumstances Vulcan may, subject to the rights of any holders of senior security interests, take control of such pledged assets. We have also agreed with Vulcan not to grant any liens on our GPCR-related intellectual property related to our cellular redistribution assay, subject to specified exceptions. If we are liquidated, Vulcan s right to receive any payments then due under our agreement would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation of our GPCR program assets. Further, the junior lien and negative pledge on our intellectual property restrict our operating and financial flexibility, potentially limiting our ability to pursue business opportunities and making it more difficult for us to respond to changes in our business.

**We may not be successful in partnering new drug targets made accessible by our GPCR program.**

To fully exploit the developments arising from our GPCR program, we intend to partner or out-license our proprietary rights associated with some of the new drug targets made accessible by our GPCR program. There can be no assurance that we will enter into any such agreements and, even if we do, that the terms of any such agreements will be favorable to us. For example, potential partners may require that we first advance the development and optimization of functionally active compounds identified from our high-throughput screening of orphan GPCRs prior to entering into a licensing or other partnering arrangement, requiring us to invest substantial resources without any certainty that we will successfully optimize one or more of the compounds or recover our investment. Potential partners may also require that we obtain the issuance of patents protecting the new drug targets and compounds that interact with those targets. We may not be successful in obtaining the issuance of such patents for the targets and compounds we intend to partner or for the targets and compounds we intend to develop ourselves and, even if we do, the breadth of our patent rights may be inadequate or may be viewed as inadequate by potential partners. Further, if we are unable to secure the issuance of patents or patents of adequate breadth, we may be unable to exclude competitors from developing and commercializing compounds that interact with GPCR targets, limiting our ability to successfully commercialize these targets either independently or with a partner.

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**Our ability to pursue the development and commercialization of products from our MASP-2 program depends on the continuation of licenses from third parties.**

Our MASP-2 program is based in part on intellectual property rights that we licensed on a worldwide exclusive basis from the University of Leicester, the UK Medical Research Council at Oxford University and Helion. The continued maintenance of these agreements requires us to undertake development activities and, if regulatory approval for marketing is obtained, to pay royalties to each of these organizations upon commercialization of a MASP-2 product. In addition, we are obligated to pay Helion up to $6.9 million upon the achievement of certain events related to a MASP-2 product, such as the filing of an IND with the FDA, initiation of clinical trials, receipt of marketing approval and reaching specified sales milestones. Our ability to continue development and commercialization of products from our MASP-2 program depends on our maintaining these exclusive licenses, which cannot be assured.

**Our ability to pursue the development and commercialization of products from our MASP-2 and Plasmin programs depends on third-party developers and manufacturers of biologic drug products.**

Any product from our MASP-2 or Plasmin programs would be a biologic drug product and we do not have the internal capability to sequence, hybridize or clone biologics or to produce them for use in clinical trials or on a commercial scale. There are only a limited number of manufacturers of biologic drug products and we cannot be certain that we can enter into supply agreements with them on commercially reasonable terms, if at all. If we are unable to obtain clinical supplies of drug product for one of these programs, clinical trials or the development of any such product for that program could be substantially delayed until we can find and qualify a manufacturer, which may increase our development costs, slow down our product development and approval process, delay receipt of product revenue and make it difficult to raise additional capital.

**Our preclinical programs may not produce products that are suitable for clinical trials or that can be successfully commercialized or generate revenue through partnerships.**

Any products from our preclinical programs, including our PDE7, MASP-2, Plasmin and GPCR programs, must successfully complete preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before entering clinical trials. Many pharmaceutical and biological products do not successfully complete preclinical testing and, even if preclinical testing is successfully completed, may fail in clinical trials. In addition, there can be no assurance that positive results from preclinical studies will be predictive of results obtained from subsequent preclinical studies or clinical trials. For example, our studies of PDE7 inhibitors in different animal models of Parkinson s disease, which may or may not be relevant to the mechanism of action of PDE7 inhibitors in humans, have produced varying results. Further, we cannot be certain that any of our preclinical product development programs will generate products that are suitable for clinical testing. For example, we have not yet generated any products from our GPCR program. We may discover that there are fewer drugable targets among the orphan GPCRs than we currently estimate and that, for those orphan GPCRs for which we identify functionally active compounds that we elect to develop independently, we are unable to develop related products that successfully complete preclinical or clinical testing. If we are unable to develop products, potential corporate partners may be unwilling to enter into partnership agreements with us. We also cannot be certain that any products that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

**Because we have a number of development programs and are considering a variety of products, we may expend our limited resources to pursue a particular product or products and fail to capitalize on products or indications that may be more profitable or for which there is a greater likelihood of success.**

Because we have limited resources, we must focus on clinical and preclinical development programs and products that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other products or other indications that later prove to have greater commercial potential and may not be able to progress development programs, including our GPCR program, as rapidly as otherwise possible. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Further, if we do not accurately evaluate the commercial potential or target market for a particular product, we may relinquish valuable rights to that product through collaboration, license or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

**It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.**

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our products, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment, as well

as on successfully defending these patents against potential third-party challenges. Our ability to protect our products from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

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The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States, and tests used for determining the patentability of patent claims in all technologies are in flux. The pharmaceutical, biotechnology and other life sciences patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. For example, in the United States, a determination of patentability by the U.S. Patent and Trademark Office, or USPTO, or validity by a court or other trier of fact requires a determination that the claimed invention has utility and is both novel and non-obvious to those of ordinary skill in the art in view of prior known publications and public information, and that the patent specification supporting the claim adequately describes the claimed invention, discloses the best mode known to the inventors for practicing the invention, and discloses the invention in a manner that enables one of ordinary skill in the art to make and use the invention, such as for our target-based technologies. The ultimate determination by the USPTO or by a court of other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may impact the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, our licensed patents or patent applications or in third-party patents.

We cannot assure you that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents, nor can we make assurances as to the scope of any claims that may issue from these pending and future patent applications or to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the United States or foreign jurisdictions, which could limit patent protection for our products and materially harm our business.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to make the inventions covered by any of our patents, if issued, or our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or products or duplicate any of our technologies or products;
- we may not be able to generate sufficient data to fully support patent applications that protect the entire breadth of developments expected to result from our development programs, including the GPCR program;
- it is possible that none of our pending patent applications will result in issued patents or, if issued, that these patents will be sufficient to protect our technology or provide us with a basis for commercially viable products or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws;
- if issued, the patents under which we hold rights may not be valid or enforceable; or

we may develop additional proprietary technologies or products that are not patentable and which are unlikely to be adequately protected through trade secrets if, for example, a competitor were to independently develop duplicative, similar or alternative technologies or products.

In addition, to the extent we are unable to obtain and maintain patent protection for one of our products or in the event such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product for follow-on indications.

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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**We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.**

If we choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party s activities do not infringe the patents.

Further, a third party may claim that we or our contract manufacturers are using inventions covered by the third party s patent rights and may go to court to stop us from engaging in the alleged infringing activity, including making, using or selling our products. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our contract manufacturers are infringing the third party s patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our contract manufacturers to pay the other party s damages for having violated the other party s patents. We have indemnified our contract manufacturers against certain patent infringement claims and thus may be responsible for any of their costs associated with such claims and actions. The pharmaceutical, biotechnology and other life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Although we have conducted searches of third-party patents with respect to our programs, these searches may not have identified all relevant third-party patents. Consequently, we cannot assure you that third-party patents containing claims covering our products, programs, technologies or methods do not exist, have not been filed, or could not be filed or issued.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents, our licensors patents, our pending applications or our licensors pending applications, or that we or our licensors were the first to invent or the first to file patent applications for inventions embodied in our technologies. Our competitors may have filed, and may in the future file, patent applications covering technologies similar to ours. Any such patent application may have priority over our or our licensors patent applications and could further require us to obtain rights to issued patents covering such technologies. If our or our licensors pending patent applications issue as patents, we can provide you no assurances that the patents will not be challenged in post-grant review or inter-parties review proceedings. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in interference derivation proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Similar patent opposition proceedings in other countries and regions may also be costly and could result in the loss of patent rights in those countries and regions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the capital necessary to continue our operations.

**The terms of our debt facility place restrictions on our operating and financial flexibility and, if we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.**

We borrowed $20.0 million pursuant to the terms the Loan Agreement with Oxford pursuant to which our outstanding principal balance was $20.0 million as of March 31, 2013. As collateral for this loan, we pledged substantially all of our assets other than intellectual property. Our agreement with Oxford restricts our ability to incur additional indebtedness, pay dividends and engage in significant business transactions such as a change of control of Omeros, so long as we owe any amounts to Oxford under the agreement. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. In addition, if we default under our agreement, Oxford may have the right to accelerate all of our repayment obligations under the agreement and to take control of our pledged assets, which include our cash, cash equivalents and short-term investments, potentially requiring us to renegotiate our agreement on terms less favorable to us. Further, if we are liquidated, Oxford s right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. An event of default under the Loan Agreement includes the occurrence of any material adverse effect upon our business operations, properties, assets, results of operations or financial condition, taken as a whole with respect to our viability, that would reasonably be expected to result in our inability to repay the loan. If Oxford declares a default upon the occurrence of any event

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that it interprets as having a material adverse effect upon us as defined under our agreement, we will be required to repay the loan immediately or to attempt to reverse Oxford s declaration through negotiation or litigation. Any declaration by Oxford of an event of default could significantly harm our business and prospects and could cause our stock price to decline. If we raise any additional debt financing, the terms of such debt could further restrict our operating and financial flexibility.

**We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.**

Our research operations produce hazardous waste products, which include chemicals and radioactive and biological materials. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply with applicable legal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. We generally contract with third parties for the disposal of such substances and store our low-level radioactive waste at our facilities until the materials are no longer considered radioactive. We may be required to incur further costs to comply with current or future environmental and safety regulations. In addition, although we carry insurance, in the event of accidental contamination or injury from these materials, we could be held liable for any damages that result and any such liability could exceed our insurance coverage and other resources.

**The loss of members of our management team could substantially disrupt our business operations.**

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies other than on the life of Gregory Demopulos, M.D., our president, chief executive officer and chairman of the board of directors and, on an interim basis, our chief financial officer and treasurer. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, could delay the execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

**We rely on highly skilled personnel and, if we are unable to retain or motivate key personnel or hire qualified personnel, we may not be able to maintain our operations or grow effectively.**

Our performance is largely dependent on the talents and efforts of highly skilled individuals. Our future success depends on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization. If we are unable to hire and train a sufficient number of qualified employees for any reason, we may not be able to implement our current initiatives or grow effectively. We have in the past maintained a rigorous, highly selective and time-consuming hiring process. We believe that our approach to hiring has significantly contributed to our success to date. If we do not succeed in attracting qualified personnel and retaining and motivating existing personnel, our existing operations may suffer and we may be unable to grow effectively.

To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

**We are involved in a lawsuit with one of our former insurance carriers that, if we lose, could materially affect our financial position and cause our stock price to decline.**

Omeros, our chief executive officer and Richard J. Klein, our former chief financial officer and treasurer, entered into the Settlement Agreement under which all of the parties released their respective claims in the lawsuit filed by Mr. Klein. CCIC was the carrier for our directors, officers and corporate liability insurance coverage at the time Mr. Klein s employment with us was terminated. On February 21, 2012, CCIC filed a complaint for a declaratory judgment against Omeros, Dr. Demopulos and Mr. Klein in the U.S. District Court for the Western District of Washington, seeking a declaration that it owes no duty to indemnify or defend us or Dr. Demopulos against the allegations raised by Mr. Klein. On May 10, 2012, Omeros and Dr. Demopulos filed counterclaims against CCIC alleging that CCIC breached its duty to defend under the insurance policy, acted unreasonably and in bad faith, and unreasonably denied a claim for coverage in violation of Washington law.

CCIC paid approximately $2.0 million of our defense costs associated with Mr. Klein s lawsuit, subject to a reservation of rights, and we paid the remaining portion of the defense costs. Additionally, in November 2012, CCIC reimbursed us $3.95 million for the $3.94 million payment we made to Mr. Klein under the terms of the Settlement Agreement as well as for the $13,000 of related employment taxes that we paid. CCIC made this payment without waiving any of its rights and without affecting any of our or our chief executive officer s counterclaims against CCIC,

including for failure to defend and bad faith, in the pending lawsuit against CCIC. While we are defending vigorously CCIC s declaratory judgment action and pursuing our counterclaims, and we intend to defend vigorously any attempt by CCIC to recover any amount it paid to us for our defense costs or for the $3.95 million reimbursement payment, we can provide no assurances regarding the outcome of the litigation with CCIC. If we are required to repay to CCIC the settlement funds or any part of our defense costs and fees borne by CCIC, or both, our financial position may be materially negatively affected and our stock price may decline.

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**The Settlement Agreement with Mr. Klein does not preclude the U.S. government from seeking recovery from us under the Federal False Claims Act or pursuing other administrative remedies against us.**

During Mr. Klein s employment with us, he used our Whistleblower Policy procedures to report to the chairman of our audit committee that we had submitted grant reimbursement claims in connection with our GPCR program to the NIH for work that we had not performed. In accordance with the Whistleblower Policy and its charter, our audit committee, with special outside counsel, commenced an independent investigation of our NIH grant and claims procedures. The investigation concluded that we had not submitted claims to the NIH for work we had not performed. In his subsequent lawsuit against us, Mr. Klein asserted the Qui Tam Claims, which were based on the same NIH grant that was the subject of Mr. Klein s whistleblower report and related NIH grants. Following an investigation of the Qui Tam Claims, in October 2011 the U.S. government declined to intervene in the lawsuit.

In our subsequent Settlement Agreement with Mr. Klein, he released all of his rights under the Qui Tam Claims. However, because the Qui Tam Claims were made on behalf of the U.S. government, Mr. Klein did not have the authority to settle them on behalf of the U.S. government and such claims accordingly were dismissed without prejudice to the U.S. government. Notwithstanding the Settlement Agreement with Mr. Klein or the U.S. government s earlier decision not to intervene with respect to the Qui Tam Claims, the U.S. government is not precluded from asserting those claims against us under the Federal False Claims Act, or from seeking administrative remedies. We are currently cooperating with an administrative review by the NIH of two grants that were the subject of the Qui Tam Claims, which could result in NIH requiring the return of up to $1.1 million in funds we received under the subject grants and other administrative remedies. If the U.S. government were to pursue claims under the Federal False Claims Act or if the NIH were to seek a return of the grant funds in an administrative action, and we elect to defend ourselves, such a defense could require us to spend significant resources and harm our relationship with the NIH, which has continued to award us grants, including for our work in GPCRs, during the course of these proceedings. Additionally, potential remedies under the Federal False Claims Act include penalties, treble damages and attorneys fees and costs. Defending or settling such an action brought by the U.S. government or the NIH may have a material negative effect on our financial position, harm our reputation and cause our stock price to decline.

**As a public company we incur increased costs and demands on management as a result of complying with the laws and regulations affecting public companies, which could affect our operating results.**

As a public company we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred, and will continue to incur, costs associated with corporate governance requirements, including the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, as well as rules implemented by the SEC and The NASDAQ Stock Market. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act and the requirements of the related SEC rules and regulations may increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage than was previously available. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

We are required to make an assessment of the effectiveness of our internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Further, our independent registered public accounting firm has been engaged to express an opinion on the effectiveness of our internal control over financial reporting. Section 404 requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting for each fiscal year. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses.

If we are unable to comply with the requirements of Section 404, management may not be able to assess whether our internal control over financial reporting is effective, which may subject us to adverse regulatory consequences and could result in a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we fail to maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner or otherwise comply with the standards applicable to us as a public company. Any failure by us to provide the required financial information in a timely manner could materially and adversely impact our financial condition and the market value of our securities.

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**Risks Related to Our Industry**

**Our competitors may develop products that are less expensive, safer or more effective, or which may otherwise diminish or eliminate the commercial success of any products that we may commercialize.**

If our competitors market products that are less expensive, safer or more effective than our future products developed from our products, that reach the market before our products, or that otherwise negatively affect the market, we may not achieve commercial success. For example, other pharmaceutical companies, many with significantly greater resources than we have, are developing PDE10 inhibitors similar to our product OMS824, and these companies may be further along in development and able to develop their products at a faster rate than we are. Pfizer Inc. recently announced that its PDE10 inhibitor product candidate failed to demonstrate efficacy in a Phase 2 clinical trial evaluating the compound in acute exacerbation of schizophrenia. This and other potential clinical trial failures of PDE10 inhibitor product candidates may negatively reflect on the ability of OMS824 to demonstrate safety and efficacy. In addition, we believe that other companies are attempting to find compounds that functionally interact with orphan GPCRs. If any of these companies are able to achieve this for a given orphan GPCR before we do, we may be unable to establish a commercially valuable intellectual property position around that orphan GPCR. Further, the failure of any future products that we may develop to effectively compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition and results of operations.

We expect to compete with other biopharmaceutical and biotechnology companies, and our competitors may:

- develop and market products that are less expensive or more effective than any future products that we may develop;
- commercialize competing products before we can launch any products that we may develop;
- operate larger research and development programs, possess commercial-scale manufacturing operations or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to remain current with rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our product discovery process that we believe we derive from our research approach and proprietary technologies and programs. In addition, physicians may continue with their respective current treatment practices, including the use of current preoperative and postoperative treatments, rather than adopt our PharmacoSurgery products.

**Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products if and when any of them are approved.**

Any product for which we obtain marketing approval, together with the manufacturing processes, post-approval clinical data, and advertising and promotional activities for such product, will be subject to continued regulation by the FDA and other regulatory agencies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or the approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products or their manufacture, or failure to comply with regulatory requirements, may result in:

restrictions on such products or manufacturing processes;

withdrawal of the products from the market;

voluntary or mandatory recalls;

fines;

suspension of regulatory approvals;

product seizures; or

injunctions or the imposition of civil or criminal penalties.

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If we are slow or unable to adapt to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we may lose marketing approval for our products when and if any of them are approved.

**Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.**

We intend to have our products marketed outside the United States. In order to market our products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may be unable to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The approval procedure varies among countries and can involve additional testing and data review. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these Risk Factors. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. The failure to obtain these approvals could harm our business.

**If we are unable to obtain adequate reimbursement from governments or third-party payors for any products that we may develop or if we are unable to obtain acceptable prices for those products, they may not be purchased or used and, as a result, our revenue and prospects for profitability could suffer.**

Our future revenue and profit will depend heavily on the availability of adequate reimbursement for the use of our approved products from governmental and other third-party payors, both in the United States and in other countries. Even if we are successful in bringing one or more products to market, these products may not be considered cost-effective, and the amount reimbursed for any product may be insufficient to allow us to sell the product profitably. Reimbursement by a third-party payor may depend on a number of factors, including the third-party payor s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each government or third-party payor is a time-consuming and costly process that will require the build-out of a sufficient staff and could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. Because none of our products has been approved for marketing, we can provide no assurances at this time regarding their cost-effectiveness and the amount, if any, or method of reimbursement. Further, we can provide no assurance that the amounts, if any, reimbursed to surgical facilities for utilization of our surgery-related products or to surgeons for the administration and delivery of these products will be considered adequate to justify the use of these products. There may be significant delays in obtaining reimbursement coverage for newly approved products and we may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payor determines that a product is eligible for reimbursement, coverage may be more limited than the purposes for which the product is approved by the FDA or foreign regulatory agencies. Increasingly, third-party payors who reimburse healthcare costs, such as government and private payors, are requiring that companies provide them with predetermined discounts from list prices and challenging the prices charged for medical products. Moreover, eligibility for coverage does not mean that any product will be reimbursed at a rate that allows us to make a profit in all cases, or at a rate that covers our costs, including research, development, manufacturing, sale and distribution. In non-U.S. jurisdictions, we must obtain separate reimbursement approvals and comply with related foreign legal and regulatory requirements. In some countries, including those in the European Union, our products may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time and expenditure of resources after the receipt of marketing approval for a product. If the reimbursement we are able to obtain for any product we develop is inadequate in light of our development and other costs or is significantly delayed, our business

could be materially harmed.

**Product liability claims may damage our reputation and, if insurance proves inadequate, these claims may harm our business.**

We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product s safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with commercialization of our products. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain and maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the commercialization of our products progresses, or that future claims against us will be covered by our product liability insurance. Although we currently have product liability insurance coverage for our clinical trials, our insurance coverage may not reimburse us or may be insufficient to reimburse us for any or all expenses or losses we may suffer. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

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**Risks Related to Our Common Stock**

**Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.**

During the 12-month period ended March 31, 2013, our stock traded as high as $13.45 per share and as low as $3.90 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors could include:

- FDA or EMA actions related to our planned NDA and MAA submissions for OMS302;
- results from our clinical development programs, including the data from our ongoing clinical development programs evaluating OMS103HP and OMS824;
- FDA or international regulatory actions related to any of our other products;
- announcements regarding the progress of our preclinical programs and our GPCR program;
- failure of any of our products, if approved, to achieve commercial success;
- quarterly variations in our results of operations or those of our competitors;
- our ability to develop and market new and enhanced products on a timely basis;
- announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;
- third-party coverage and reimbursement policies;
- additions or departures of key personnel;
- commencement of, or our involvement in, litigation;
- our ability to meet our repayment and other obligations under our loan facility with Oxford, pursuant to which our outstanding principal balance was $20.0 million as of March 31, 2013;
- the inability of our contract manufacturers to provide us with adequate commercial supplies of our products;

changes in governmental regulations or in the status of our regulatory approvals;

changes in earnings estimates or recommendations by securities analysts;

any major change in our board or management;

general economic conditions and slow or negative growth of our markets; and

political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the commercialization of our product and products may be delayed.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company s securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management s attention and resources.

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**We expect that we will seek additional capital in the future; however, such capital may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing shareholders would experience further dilution.**

Although we expect to seek additional capital, we cannot be certain that it will be available to us on acceptable terms, if at all. Continued disruptions in the global equity and credit markets may further limit our ability to access capital. To the extent that we raise additional funds by issuing equity securities, including pursuant to our Sales Agreement with MLV, our shareholders may experience significant dilution. Any debt financing, if available, may restrict our operations similar to our debt facility with Oxford. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or one or more of our other research and development initiatives. We also could be required to seek collaborators for one or more of our current or future products at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might be available or to relinquish or license on unfavorable terms our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves. We also may have insufficient funds or otherwise be unable to advance our preclinical programs, such as potential new drug targets developed from our GPCR program, to a point where they can generate revenue through partnerships, collaborations or other arrangements. Any of these events could significantly harm our business and prospects and could cause our stock price to decline.

**If we sell shares of our common stock under the Sales Agreement with MLV, our existing shareholders will experience immediate dilution and, as a result, our stock price may go down.**

In December 2012, we entered into the Sales Agreement with MLV as sales agent under which we may sell up to $60.0 million of our common stock by any method deemed to be an at-the-market offering under SEC rules. If we sell shares under the Sales Agreement, such sales will dilute our existing shareholders and could cause the market price of our common stock to decline significantly. Although MLV is precluded from shorting our stock during the term of the Sales Agreement, the ability to sell shares under the Sales Agreement and any sales of our common stock under the Sales Agreement, should we elect to use it, could encourage short sales by third parties, which could contribute to the further decline of our stock price.

**Future sales of shares by holders of outstanding warrants and options could cause our stock price to decline.**

Approximately 8.1 million shares of common stock that are either subject to outstanding warrants or subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

**Anti-takeover provisions in our charter documents and under Washington law could make an acquisition of us, which may be beneficial to our shareholders, difficult and prevent attempts by our shareholders to replace or remove our current management.**

Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of shareholders to fill board vacancies and the ability of our board of directors to issue preferred stock without shareholder approval. In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of shareholders owning ten percent or more of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

**We have never declared or paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.**

Our business requires significant funding, and we have not generated any material revenue. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Additionally, under our Loan Agreement with Oxford, we have agreed not to pay any dividends so long as we have any outstanding obligations under the agreement. Therefore, we currently do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a rise in the market price of our common stock, which is uncertain and unpredictable, will be your sole source of potential gain in the foreseeable future, and you should not rely on an investment in our common stock for dividend income.

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**ITEM 6. EXHIBITS**

| Exhibit Number | Description |
|---|---|
| 4.1* | Notice Regarding the Extension of the Expiration Date to March 29, 2014 of Warrants to Purchase up to an Aggregate of 197,478 Shares of the Common Stock of the Registrant |
| 10.1 | Amendment No. 2 to License Agreement with an effective date of January 25, 2013 between Omeros Corporation and Daiichi Sankyo Co., Ltd. |
| 12.1 | Ratio of Earnings to Fixed Charges |
| 31.1 | Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1 | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2 | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS** | XBRL Instance Document |
| 101.SCH** | XBRL Taxonomy Extension Schema Document |
| 101.CAL** | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF** | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB** | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE** | XBRL Taxonomy Extension Presentation Linkbase Document |

* Incorporated by reference from the registrant s Current Report on Form 8-K filed on March 29, 2013 (File No. 001-34475).

** XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under those sections.
Portions of this exhibit are redacted in accordance with a request for confidential treatment.

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**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 thereunto duly authorized.

**OMEROS CORPORATION**

Date: May 9, 2013

/s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D.
President, Chief Executive Officer

and Chairman of the Board of Directors