OMEROS CORP
Form 10-Q
August 07, 2012
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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 June 30, 2012

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)
1420 Fifth Avenue, Suite 2600	
Seattle, Washington	98101
(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 August 2, 2012, the number of outstanding shares of the registrant s common stock, par value $0.01 per share, was 25,862,901.

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OMEROS CORPORATION

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2012

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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)

	June 30, 2012 (unaudited)	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 7,268	$ 4,005
Short-term investments		20,565
Grant and other receivables	767	876
Prepaid expenses and other current assets	485	502
Total current assets	8,520	25,948
Deferred offering costs	235	
Property and equipment, net	660	739
Restricted cash	563	193
Other assets	88	102
Total assets	$ 10,066	$ 26,982
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 1,285	$ 2,002
Accrued expenses	6,016	5,340
Deferred revenue	3,738	5,748
Current portion of notes payable	6,210	5,895
Total current liabilities	17,249	18,985
Notes payable, less current portion	10,345	13,551
Other liabilities	3,009	
Commitments and contingencies		
Shareholders equity:		
Preferred stock, par value $0.01 per share:		
Authorized shares 20,000,000 at June 30, 2012 (unaudited) and December 31, 2011; Issued and outstanding shares none		
Common stock, par value $0.01 per share:		
Authorized shares 150,000,000 at June 30, 2012 (unaudited) and December 31, 2011; Issued and outstanding shares 22,497,047 and 22,430,234 at June 30, 2012 (unaudited) and December 31, 2011, respectively	225	224
Additional paid-in capital	172,805	170,355
Accumulated deficit	(193,567)	(176,133)
Total shareholders deficit	(20,537)	(5,554)

Total liabilities and shareholders equity	$ 10,066	$ 26,982

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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenue	$ 1,526	$ 1,155	$ 3,022	$ 2,394
Operating expenses:				
Research and development	7,558	4,077	14,804	9,502
General and administrative	2,212	2,027	4,534	4,291
Total operating expenses	9,770	6,104	19,338	13,793
Loss from operations	(8,244)	(4,949)	(16,316)	(11,399)
Investment income	6	14	18	31
Interest expense	(453)	(527)	(947)	(820)
Other income (expense), net	152	171	(189)	355
Net loss	$ (8,539)	$ (5,291)	$ (17,434)	$ (11,833)
Comprehensive loss	$ (8,539)	$ (5,291)	$ (17,434)	$ (11,833)
Basic and diluted net loss per share	$ (0.38)	$ (0.24)	$ (0.78)	$ (0.54)
Weighted-average shares used to compute basic and diluted net loss per share	22,466,540	22,167,629	22,450,722	22,112,110

See notes to consolidated financial statements

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OMEROS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Six Months Ended June 30,	
	2012	**2011**
Operating activities		
Net loss	$ (17,434)	$ (11,833)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	165	227
Stock-based compensation expense	1,700	1,005
Non-cash interest expense	200	151
Warrant modification expense	511	
Changes in operating assets and liabilities:		
Grant and other receivables	108	631
Prepaid expenses and other current and noncurrent assets	(378)	(27)
Deferred offering costs	(235)	
Accounts payable and accrued expenses	(62)	(3,152)
Deferred revenue	(1,950)	(1,202)
Other liabilities	3,009	
Net cash used in operating activities	(14,366)	(14,200)
Investing activities		
Purchases of property and equipment	(145)	(1,193)
Purchases of investments		(9,000)
Proceeds from the sale of investments	20,565	15,000
Net cash provided by investing activities	20,420	4,807
Financing activities		
Proceeds from borrowings under note payable, net of loan origination costs and prepayment penalty		9,942
Payments on notes payable	(3,031)	(41)
Proceeds from issuance of common stock upon exercise of stock options	240	373
Net cash (used in) provided by financing activities	(2,791)	10,274
Net increase in cash and cash equivalents	3,263	881
Cash and cash equivalents at beginning of period	4,005	3,278
Cash and cash equivalents at end of period	$ 7,268	$ 4,159
Supplemental cash flow information		
Cash paid for interest	$ 769	$ 599
Reduction of equipment cost basis due to assets purchased with grant funding	$ 59	$ 1,636

See notes to consolidated financial statements

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OMEROS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 product candidates are derived from our proprietary PharmacoSurgery platform designed to improve clinical outcomes of patients undergoing arthroscopic, ophthalmological, 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 accounting principles generally accepted in the United States of America, 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 June 30, 2012 and for the three and six months ended June 30, 2012 and 2011, includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The consolidated balance sheet at December 31, 2011 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, 2011.

Principals 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.

Adoption of Standards

In June 2011, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update, or ASU, related to the presentation of comprehensive income which requires companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of changes in shareholders equity. The standard does not change the items that must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. This standard, which must be applied retroactively, was effective for interim and annual periods beginning after December 15, 2011. We adopted the standards on January 1, 2012 and have presented a combined statement of operations and comprehensive loss in our accompanying financial statements.

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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 and six months ended June 30, 2012 and 2011 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:

	June 30,	
	2012	2011
Outstanding options to purchase common stock	4,132,858	3,322,064
Warrants to purchase common stock	609,016	609,016
Total	4,741,874	3,931,080

Note 3 Cash, Cash Equivalents and Short-term Investments

As of June 30, 2012, all investments were sold and the proceeds were reinvested in cash and cash equivalents, and as of December 31, 2011, all investments were classified as short-term and available-for-sale on the accompanying balance sheet. We did not own any securities with unrealized loss positions as of June 30, 2012 or December 31, 2011. 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:

	June 30, 2012			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets:				
Money-market funds classified as cash equivalents and restricted cash	$ 6,983	$	$	$ 6,983
Total	$ 6,983	$	$	$ 6,983

	December 31, 2011			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets:				

Money-market funds classified as cash equivalents and restricted cash	$ 2,587	$	$ 2,587
Money-market funds classified as short-term investments	20,565		20,565
Total	$ 23,152	$	$ 23,152

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Note 5 Certain Balance Sheet Accounts

Accrued Expenses

Accrued expenses consisted of the following:

	June 30, 2012	December, 31 2011
	(in thousands)	
Clinical trials	$ 3,297	$ 3,532
Contract research	954	694
Employee compensation	490	364
Deferred offering costs	224	
Other accruals	1,051	750
Accrued expenses	$ 6,016	$ 5,340

Note 6 Notes Payable

On October 21, 2010, we entered into a loan and security agreement with Oxford Finance Corporation, or Oxford, pursuant to which Oxford agreed to lend us up to $20.0 million in two tranches of $10.0 million each. Upon signing the agreement, we borrowed the first tranche of $10.0 million, or Tranche 1. On March 25, 2011, we borrowed the second tranche of $10.0 million, or Tranche 2. Interest on Tranche 1 and Tranche 2 accrues at annual fixed rates of 8.55% and 8.56%, respectively. As security for our obligations under the Oxford agreement, we granted Oxford a security interest in substantially all of our assets, excluding our intellectual property.

Upon the last payment date of the amounts borrowed from Oxford, we will be required to pay Oxford a final payment fee equal to 5.0% of Tranche 1 ($500,000) and 4.0% of Tranche 2 ($400,000). The final payment fees were recorded as a discount to the notes and are being amortized to interest expense using the effective-interest method over the repayment term of the initial loan amount. In connection with Tranche 1 and Tranche 2, we incurred debt issuance costs of $169,000 and $58,000, respectively, that were capitalized and included in other assets in the balance sheets. The debt issuance costs are being amortized to interest expense using the effective interest method over the term of the initial loan amount. For the three months ended June 30, 2012 and 2011, total non-cash interest expense associated with our borrowings under Tranche 1 and Tranche 2 includes amortization of the discount of $78,000 and $76,000, respectively, and amortization of debt issuance costs of $19,000 and $19,000, respectively. For the six months ended June 30, 2012 and 2011, total non-cash interest expense associated with our borrowings under Tranche 1 and Tranche 2 includes amortization of the discount of $161,000 and $118,000, respectively, and amortization of debt issuance costs of $39,000 and $33,000, respectively. As of June 30, 2012 and December 31, 2011, the remaining unamortized balance of the debt discount is $428,000 and $589,000, respectively, and the remaining unamortized balance of the debt issuance costs is $106,000 and $145,000, respectively.

Note 7 Revenue

We receive Small Business Innovative Research, or SBIR, grants from the National Institutes of Health, or NIH, which are used to support the research and development of our product candidates. We recorded revenue related to these grants of $329,000 and $121,000 for the three months ended June 30, 2012 and 2011, respectively, and $489,000 and $209,000 for the six months ended June 30, 2012 and 2011, respectively. As of June 30, 2012, $1.4 million remained available under these grants.

On December 18, 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 candidate for the treatment of schizophrenia. Through June 30, 2012, we have received a total of $5.7 million from SMRI in the form of grant and equity funding. As of June 30, 2012, all amounts pertaining to this agreement previously recorded as deferred revenue in the accompanying balance sheet have been recognized as revenue. We recognized no revenue under the SMRI funding agreement in 2012 and $94,000 and $227,000 for the three and six months ending June 30, 2011, respectively. See additional discussion of the SMRI agreement under Note 8.

On October 21, 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 from Vulcan. 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 of the costs of assets purchased in direct proportion to the related GPCR expenses as they are incurred. Also on October 21, 2010, we entered into an agreement with the State of Washington s Life Sciences Discovery Fund Authority, 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 June 30, 2012 and 2011, we have recorded reductions to the Vulcan deferred revenue balance of $1.3 million and $401,000, respectively, which includes $1.2 million and $387,000 recognized as revenue and $60,000 and $14,000 recorded as cost reductions to assets, respectively. For the six months ended June 30,

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2012 and 2011, we have recorded reductions to the Vulcan deferred revenue balance of $2.0 million and $958,000, respectively, which includes $1.9 million and $934,000 recognized as revenue and $60,000 and $24,000 recorded as cost reductions to assets, respectively. As of June 30, 2012, $3.7 million in deferred revenue pertaining to the platform development funding agreement with Vulcan was recorded in the accompanying balance sheet. We recognized all remaining revenue under the LSDF agreement during the first quarter of 2012. For the three months ended June 30, 2011, we recognized revenue under the LSDF agreement of $553,000 and have recorded cost reductions to assets of $1.6 million. For the six months ended June 30, 2012 and 2011, respectively, we recognized revenue of $624,000 and $1.0 million. For the six months ended June 30, 2012, we recorded no cost reductions to assets and for the six months ended June 30, 2011, we recorded cost reductions to assets of $1.6 million. See additional discussion of the Vulcan and LSDF agreements under Note 8.

Note 8 Commitments and Contingencies

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 June 30, 2012, the maximum amount of royalties payable by us is $12.8 million. We have not paid any such royalties through June 30, 2012.

On February 25, 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. On February 23, 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 applications.

On March 3, 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. On January 31, 2011, we amended the agreement to include addiction and compulsive disorders in the field of use. Under the amended agreement, we agreed to make milestone payments to Daiichi Sankyo of up to $30.2 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. 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.

On April 23, 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 made a one-time payment to Helion of $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 with the U.S. Food and Drug Administration; 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 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. After we have received approximately $1.5 billion of cumulative net proceeds, 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

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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.

On November 22, 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.

As described in Part II, Item I of this Quarterly Report on Form 10-Q, we are involved in litigation brought against us by our former chief financial officer, Richard J. Klein. Mr. Klein has asserted claims related to an alleged wrongful discharge of his employment and qui tam claims under the Federal False Claims Act related to certain NIH grants. Mr. Klein seeks, among other things, double damages in an amount to be proven at trial, actual litigation expenses, damages for loss of past and future earnings and his reasonable attorneys fees. The U.S. government filed a notice of its election to decline intervention in the qui tam claims, but this election does not prevent Mr. Klein from continuing these claims or his other claims. Thereafter, the court issued an order granting our motion to dismiss the majority of Mr. Klein s qui tam claims for failing to meet statutory requirements, leaving pending only qui tam claims related (1) to our alleged obligations stemming from grant funds drawn down by nura prior to our acquisition of nura in 2006 and (2) to timekeeping allegations regarding an NIH grant. We are vigorously defending ourselves against Mr. Klein s claims and seek, among other things, our attorneys fees and costs incurred in defending this action. Although we deny Mr. Klein s allegations and believe that we have substantial and meritorious defenses to his remaining claims, the outcome of the litigation cannot be assessed with certainty and the ultimate financial impact of the lawsuit is not yet determinable. Therefore, no provision for loss, if any, has been recorded in the financial statements.

Costs associated with defense of the lawsuit filed by Mr. Klein have to date been paid in part, subject to a reservation of rights, by Carolina Casualty Insurance Company, or CCIC, which was the carrier for our Directors, Officers and Corporate Liability Insurance Coverage that was in place at the time Mr. Klein s employment with us was terminated. On February 21, 2012, CCIC filed a complaint for a declaratory judgment against us, our chief executive officer and Mr. Klein seeking a declaration that CCIC owes no duty to indemnify or defend us or our chief executive officer against the allegations raised by Mr. Klein. We expect that CCIC will continue to pay a portion of the defense costs related to the qui tam claims in this lawsuit while these matters are pending. We intend to defend the declaratory judgment action filed by CCIC, and 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 pay our defense costs related to the lawsuit filed by Mr. Klein. The ultimate financial impact of this action is not yet determinable. Therefore, no provision for loss, if any, has been recorded in the financial statements.

Lease Agreement

On January 27, 2012, we entered into a lease with BMR-201 Elliott Avenue LLC, for approximately 64,500 square feet of office and laboratory space in the building located at 201 Elliott Avenue West, Seattle, Washington, which will be known as The Omeros Building. The premises leased by us will replace the separate office and laboratory spaces that we currently occupy. The initial term of the lease is 15 years with two options to extend the lease term, each by 5 years. The expected term commencement date is October 1,

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2012. The aggregate rent payable under the initial term of the lease is approximately $51.1 million. The lease required us to provide the landlord with $563,000 as a security deposit, which is recorded as restricted cash on the accompanying balance sheet as of June 30, 2012. Additionally, the landlord has agreed to reimburse us for up to $650,000 in expenses incurred by us in connection with the leased premises, and on March 30, 2012 the landlord paid us a $3.0 million cash lease incentive. As of June 30, 2012, we recorded as deferred rent, a net amount of $3.2 million related to the cash lease incentive and direct costs incurred in connection with consummating the lease. All lease incentives and direct costs will be amortized over the initial term of the lease.

On January 30, 2012, in connection with the new lease agreement for The Omeros Building, we gave notice to the landlord of our current corporate office space that we were terminating the lease for that space on January 30, 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 has been changed to March 29, 2013. 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 date to determine the incremental change in their fair value and recorded a change in fair value of $(511,000) in other income (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. On January 1, 2012, in accordance with the 2008 Plan annual increase provisions, the authorized shares in the 2008 Plan increased by 1,121,511 shares.

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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Weighted-average estimated fair value	$ 7.09	$ 3.07	$ 3.28	$ 3.65
Weighted-average Assumptions:				
Expected volatility	86%	81%	89%	81%
Expected term (in years)	5.50	5.50	5.71	5.68
Risk-free interest rate	0.78%	1.88%	1.05%	2.13%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

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 June 30,	Six Months Ended June 30,

	2012	2011	2012	2011
			(in thousands)	
Research and development	$ 285	$ 210	$ 853	$ 458
General and administrative	284	337	847	547
Total	$ 569	$ 547	$ 1,700	$ 1,005

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Stock options granted to non-employees are accounted for using the fair-value approach. The fair value of non-employee option grants are estimated using the Black-Scholes option-pricing model and are re-measured over the vesting term as earned. The estimated fair value is charged to expense over the applicable service period.

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, 2011	3,006,567	$ 3.32		
Granted	1,245,900	4.54		
Exercised	(66,813)	3.59		
Forfeited	(52,796)	6.25		
Balance at June 30, 2012	4,132,858	$ 3.65	6.93	$ 26,306
Vested and expected to vest at June 30, 2012	1,249,272	$ 5.34	8.98	$ 5,831
Exercisable at June 30, 2012	2,746,996	$ 2.80	5.90	$ 19,819

At June 30, 2012, excluding non-employee stock options, there were 1,356,598 unvested options outstanding that will vest over a weighted-average period of 2.5 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these shares is $4.3 million.

Note 11 Subsequent Events

Public Offering

On July 2, 2012, we completed a public offering pursuant to which we sold 3,365,854 shares of our common stock at a price of $10.25 per share. After deducting underwriting discounts and other estimated offering expenses payable by us, we received net proceeds from the transaction of $32.4 million.

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

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, 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 complete the second Phase 3 trial for OMS302 during the second half of 2012;*
- *our ability to complete the first Phase 3 trial for OMS103HP in arthroscopic partial meniscectomy surgery during the second half of 2012;*

our ability to begin the second Phase 3 trial for OMS103HP following discussions with European regulatory authorities;

our ability to raise capital under our equity line financing facility or otherwise access the capital markets;

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our expectations regarding the clinical benefits of our potential products;

our expectation that 2014 is the earliest year in which any of our potential 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; and

our expected financial position, performance, growth, expenses, the magnitude of our net losses and the availability of resources.

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 Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2011. As a result of such factors, the 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. Also, 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 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.

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 are derived from our proprietary PharmacoSurgery platform designed to improve clinical outcomes of patients undergoing arthroscopic, ophthalmological, 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 four 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 potential products and programs, we have retained all manufacturing, marketing and distribution rights.

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OMS302, one of our co-lead PharmacoSurgery potential products, is currently being evaluated in a Phase 3 clinical program in patients undergoing intraocular lens replacement, or ILR, surgery. We expect this clinical program to consist of two trials that will enroll both cataract surgery and refractive lens exchange patients. In the first Phase 3 clinical trial, which we completed in March 2012, OMS302 demonstrated statistically significant superiority over placebo in maintenance of intraoperative mydriasis (pupil dilation) and reduction of postoperative pain. We are now conducting the second Phase 3 clinical trial, which is evaluating the same efficacy and safety measures as the earlier successful Phase 2b and Phase 3 clinical trials. We expect to receive data from the ongoing Phase 3 clinical trial in the second half of 2012.

OMS103HP, our other co-lead PharmacoSurgery potential product, is being evaluated in a Phase 3 clinical program for its safety and ability to improve postoperative joint function and reduce pain following arthroscopic partial meniscectomy surgery. We intend this clinical program to consist of two trials and expect data from the first trial in the second half of 2012. We are preparing for discussions with European regulatory authorities regarding the second Phase 3 clinical trial and, assuming sufficient resources, plan to begin that trial following completion of those discussions. In the first quarter of 2011, we announced that OMS103HP failed to meet pre-specified efficacy endpoints in a Phase 3 clinical program in patients undergoing arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery. We were unable to draw any conclusions about OMS103HP s effect in the Phase 3 ACL program due to confounding factors, and we have no plans to conduct additional ACL reconstruction trials at this time.

Our third PharmacoSurgery potential product, OMS201, is being developed for use during urological surgery, including uroendoscopic procedures. During the fourth quarter of 2010, we completed a Phase 1/Phase 2 clinical trial in patients undergoing ureteroscopic removal of ureteral or renal stones. The data showed that OMS201 was well tolerated by the patients in this trial. Based on these data, we are planning to conduct subsequent trials to evaluate the efficacy and safety of OMS201.

In addition to our PharmacoSurgery platform, we have a pipeline of other product development programs targeting inflammation, coagulopathies and disorders of the central nervous system. In our PPARg program, we are developing proprietary compositions that include PPARg agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine and alcohol. In our PDE10 program, we are developing proprietary compounds to treat cognitive disorders, including schizophrenia and Huntington s disease. Our PDE7 program is based on our discoveries of previously unknown links between PDE7 and (1) any movement disorder, such as Parkinson s disease, and (2) addiction and compulsive disorders, and we are developing proprietary compounds for the treatment of these and other related disorders. In our MASP-2 program, we are developing proprietary MASP-2 antibody therapies to treat disorders associated with complement-activated inflammation, and we are advancing novel antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma as well as for hyperfibrinolytic states (e.g., liver disease) in our Plasmin program.

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. We have already announced that we have identified and confirmed sets of compounds that interact selectively with, and modulate signaling of, 37 orphan GPCRs. During the fourth quarter of 2010, we entered into an agreement with Vulcan pursuant to which we received $20.0 million for our GPCR program. Also during the same quarter, we entered into an agreement with the LSDF under which we received a $5.0 million grant award that was paid to reimburse us for expenses we incurred and equipment purchases related to our GPCR program. In exchange for these payments, we agreed to pay to Vulcan and LSDF a portion of net proceeds that we receive from the GPCR program. We also issued to the Vulcan affiliate three warrants to purchase our common stock, each with a five-year term and exercisable for up to 133,333 shares, with exercise prices of $20, $30 and $40 per share, respectively. Following the receipt of the $20.0 million from Vulcan, we purchased from Patobios intellectual property assets related to an assay technology for use in the GPCR program. The purchase price for these assets was approximately $10.8 million, of which approximately $7.6 million was paid in cash and $3.2 million was paid in shares of our common stock. We have no royalty or milestone payment obligations to Patobios.

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As of June 30, 2012, our accumulated deficit was $193.6 million and total shareholders deficit was $20.5 million. We recognized net losses of $8.5 million and $5.3 million for the three months ended June 30, 2012 and 2011, respectively, and $17.4 million and $11.8 million for the six months ended June 30, 2012 and 2011, 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 potential products. Compared to 2011, 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 commercial launch of OMS302, if it is approved.

Revenue

Through June 30, 2012, our revenue has consisted of grant funding from third parties and revenue recognized in connection with funding from Vulcan and LSDF. Other than grant funding, we do not expect to receive any revenue from our products until we receive regulatory approval and commercialize the products or until we potentially enter into collaborative agreements with third parties for the development and commercialization of our products. As discussed below, we do not expect any of our current potential 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 potential products and research programs.

Research and Development Expenses

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;
- external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, 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.

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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
	(in thousands)			
Direct external expenses:				
Clinical research and development:				
OMS302	$ 2,170	$ 211	$ 3,818	$ 602
OMS103HP	915	546	1,905	1,949
Other clinical programs	70	183	98	190
Total clinical research and development	3,155	940	5,821	2,741
Preclinical research and development	1,692	620	3,090	1,281

Total direct external expenses	4,847	1,560	8,911	4,022
Internal, overhead and other expenses	2,426	2,307	5,040	5,022
Stock-based compensation expense	285	210	853	458
Total research and development expenses	$ 7,558	$ 4,077	$ 14,804	$ 9,502

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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.

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 potential product, as well as on-going assessments of each product s commercial potential. In addition, we cannot forecast with any degree of certainty which potential 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 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. We do not expect any of our current potential 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.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, legal, finance, accounting, business development, information technology and human resource functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent costs and professional fees for legal, consulting and audit services.

Investment Income

Investment income consists of realized gains on sales of investments and interest earned on our cash, cash equivalents and short-term investments.

Interest Expense

Interest expense consists of interest on our notes payable and the amortization of both the related discount and debt issuance costs.

Other (Expense) Income, net

Other (expense) income, net consists primarily of rental income received under subleases for use of a portion of our vivarium and laboratory facility and warrant expense resulting from the extension in 2012 of the expiration date of certain warrants to purchase our common stock.

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Results of Operations

Comparison of Three Months Ended June 30, 2012 and June 30, 2011

Revenue. Revenue was $1.5 million for the three months ended June 30, 2012 compared to $1.2 million for the three months ended June 30, 2011. This increase was primarily due to an increase in revenue recognized in connection with preclinical research funded by grants from the NIH and an increase in revenue recognized in connection with the Vulcan agreement for our GPCR program.

Research and Development Expenses. Research and development expenses were $7.6 million for the three months ended June 30, 2012 compared to $4.1 million for the three months ended June 30, 2011. The increase in 2012 was primarily due to higher clinical trial expenses associated with enrollment in our Phase 3 clinical trials evaluating OMS302 and OMS103HP and higher expenses in connection with our PDE10 and MASP programs.

General and Administrative Expenses. General and administrative expenses were $2.2 million for the three months ended June 30, 2012 compared to $2.0 million for the three months ended June 30, 2011. The increase in 2012 was primarily due to higher patent costs.

Interest Expense. Interest expense was $453,000 for the three months ended June 30, 2012 compared to $527,000 for the three months ended June 30, 2011. The decrease was due to a lower average notes payable balance during the 2012 period.

Other Income (Expense), net. Other income, net, was $152,000 for the three months ended June 30, 2012 compared to $171,000 for the three months ended June 30, 2011. The decrease relates primarily to lower rental income received under subleases.

Comparison of Six Months Ended June 30, 2012 and June 30, 2011

Revenue. Revenue was $3.0 million for the six months ended June 30, 2012 compared to $2.4 million for the six months ended June 30, 2011. This increase was primarily due to an increase in revenue recognized in connection with preclinical research funded by grants from the NIH and an increase in revenue recognized in connection with the Vulcan agreement. This increase was partially offset by a decrease in revenue recognized in connection with our agreements with LSDF and SMRI as we recognized all remaining revenue under those agreements during the first quarter of 2012 and second quarter of 2011, respectively.

Research and Development Expenses. Research and development expenses were $14.8 million for the six months ended June 30, 2012 compared to $9.5 million for the six months ended June 30, 2011. The increase in 2012 was primarily due to higher clinical trial expenses associated with enrollment in our Phase 3 clinical trials evaluating OMS302 and OMS103HP, higher expenses in connection with our PDE10 and MASP programs and an increase in stock-based compensation expense related to company-wide options granted in the 2012 period with April 2011 vesting start dates.

General and Administrative Expenses. General and administrative expenses were $4.5 million for the six months ended June 30, 2012 compared to $4.3 million for the six months ended June 30, 2011. The increase in 2012 was primarily due to higher employee costs and higher stock-based compensation expense related to company-wide options granted in the 2012 period with April 2011 vesting start dates, partially offset by various individually insignificant decreases.

Investment Income. Investment income was $18,000 for the six months ended June 30, 2012 as compared to $31,000 for the six months ended June 30, 2011. The decrease is due primarily to lower average investment balances in 2012.

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Interest Expense. Interest expense was $947,000 for the six months ended June 30, 2012 compared to $820,000 for the six months ended June 30, 2011. The increase was due to a higher average notes payable balance during the 2012 period.

Other Income (Expense), net. Other expense, net was $189,000 for the six months ended June 30, 2012 compared to other income, net of $355,000 for the six months ended June 30, 2011. On March 28, 2012, we extended the expiration date of warrants to purchase an aggregate of 197,478 shares of our common stock. We recognized other expense of $511,000 in connection with the warrant modification.

Liquidity and Capital Resources

We have financed our operations primarily through (1) private and public placements of equity securities for proceeds totaling $171.5 million, $32.4 million of which was received, after estimated expenses, in a public offering completed on July 2, 2012 pursuant to which we sold 3,365,854 shares of common stock at a price of $10.25 per share; (2) through two debt facilities with loan proceeds totaling $37.0 million, $9.0 million of which was used to pay off the remaining balance of the first facility; and (3) our GPCR program funding agreement with Vulcan pursuant to which we received $20.0 million. Additionally, we received a $3.0 million cash lease incentive payment in the first quarter of 2012 related to our new office and laboratory lease with BMR-201 Elliott Avenue LLC, or BMR. As of June 30, 2012, we had $7.3 million in cash, cash equivalents and short-term investments, which does not include the $32.4 million in net proceeds received from our public offering completed on July 2, 2012. Our cash, cash equivalents and short-term investment balances are or were 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. As of June 30, 2012, all investments were sold and the proceeds were reinvested in cash and cash equivalents.

Comparison of Six Months Ended June 30, 2012 and June 30, 2011

Operating Activities. Net cash used in operating activities was $14.4 million and $14.2 million for the six months ended June 30, 2012 and 2011, respectively. Expenditures related to operating activities in these periods were primarily the result of costs associated with research and development expenses and general and administrative expenses in support of our operations. The increase in net cash used in operating activities was primarily due to increased research and development expenses, including higher costs to support our Phase 3 clinical trials evaluating OMS302 and OMS103HP, partially offset by the $3.0 million cash lease incentive payment received from BMR during the first quarter of 2012.

Investing Activities. Net cash provided by investing activities was $20.4 million and $4.8 million for the six months ended June 30, 2012 and 2011, respectively. Investing activities, other than the purchase and sale 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. These amounts primarily relate to shifts between cash and cash equivalents and short-term investments. 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. Net cash used by financing activities was $2.8 million for the six months ended June 30, 2012, primarily related to principal payments on our Oxford notes. Net cash provided by financing activities was $10.3 million for the six months ended June 30, 2011, primarily as a result of our borrowing of $10.0 million under tranche two of our loan from Oxford in March 2011, partially offset by principal payments on the Oxford notes.

Azimuth Equity Line Financing Facility

In May 2011, we entered into an equity line financing facility with Azimuth Opportunity, Ltd., or Azimuth, pursuant to which we may sell up to $40.0 million of our shares of common stock over a 24-month term. This facility replaced a prior equity line financing facility, which we entered into with Azimuth on July 28, 2010 but had not accessed. Under the

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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 and a limit of 2.5% of our market capitalization at the time of the draw down, which limit may be waived by our mutual agreement. 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. In connection with this facility, we entered into a new 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 upon settlement of each such sale. Pursuant to the agreement, we also reimbursed $10,000 of FWG/Reedland s legal expenses in connection with a filing that was made by FWG/Reedland pursuant to FINRA Rule 5110.

Stanley Medical Research Institute Funding Agreement

In December 2006, we entered into a funding agreement with SMRI to develop a proprietary product that inhibits PDE10 for the treatment of schizophrenia. Under the agreement, we may receive grant and equity funding upon achievement of product development milestones through Phase 1 clinical trials totaling $9.0 million, subject to our mutual agreement with SMRI. As of June 30, 2012, we had received $5.7 million from SMRI, $2.5 million of which was recorded as revenue and $3.2 million of which was recorded as equity funding.

Oxford Loan and Security Agreement

In October 2010, we entered into a loan and security agreement with Oxford pursuant to which we borrowed $20.0 million in two tranches of $10.0 million each. Upon signing the agreement, we borrowed the first tranche of $10 million, or Tranche 1, approximately $9.0 million of which we used to repay all outstanding amounts, including a 1.0% prepayment fee, due under our loan and security agreement with another lender. In March 2011, we borrowed the second tranche of $10.0 million, or Tranche 2.

We are using the proceeds remaining from Tranche 1 and Tranche 2 for working capital and general business purposes. Interest on Tranche 1 and Tranche 2 accrues at annual fixed rates of 8.55% and 8.56%, respectively. Payments due under Tranche 1 and Tranche 2 were interest only, payable monthly, in arrears, through October 31, 2011. Beginning November 1, 2011, 36 payments of principal and interest became payable monthly, in arrears. All unpaid principal and accrued and unpaid interest are due and payable on the maturity date, October 21, 2014.

The Oxford 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, repurchase stock, in each case subject to customary exceptions for a credit facility of this size and type. The Oxford agreement contains no cash covenant. The Oxford agreement includes customary events of default that include, among other things, non-payment defaults, inaccuracy of representations and warranties, covenant defaults, a material adverse change default, cross default to material indebtedness, bankruptcy and insolvency defaults, material judgment defaults, and a change of control default. The occurrence of an event of default could result in the acceleration of the obligations under the Oxford agreement. Under certain circumstances, a default interest rate will apply on all obligations during the existence of an event of default under the Oxford agreement at a per annum rate equal to 5.0% above the otherwise applicable interest rate.

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In connection with our draw-downs of Tranche 1 and Tranche 2, we incurred debt issuance costs of $169,000 and $58,000, respectively, that were capitalized and included in other assets in the balance sheets. Included in the debt issuance costs of each tranche is a one-time facility fee payment to Oxford of $50,000. Upon the last payment date of the amounts borrowed from Oxford, we will be required to pay Oxford a final payment fee equal to 5.0% of Tranche 1 ($500,000) and 4.0% of Tranche 2 ($400,000). The final payment fees were recorded as a discount to the loan and are being amortized to interest expense using the effective interest method over the repayment term of the initial loan amount. We may prepay all, but not less than all, of the outstanding principal and accrued and unpaid interest under either Tranche 1 or Tranche 2 of the Oxford loan agreement at any time upon prior notice to Oxford and the payment of a fee equal to 1% of the then-outstanding principal amount. As security for our obligations under the Oxford agreement, we granted Oxford a security interest in substantially all of our assets, excluding intellectual property.

Funding Requirements

On July 2, 2012, we completed a public offering pursuant to which we sold 3,365,854 shares of our common stock at a price of $10.25 per share. After deducting underwriting discounts and other estimated offering expenses payable by us, our estimated net proceeds from the transaction were $32.4 million. We believe that our existing cash, cash equivalents and short-term investments and available capital under our committed equity line financing facility will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months. Our assumptions include our ability to raise capital under our $40.0 million equity line financing facility with Azimuth.

Because of the numerous risks and uncertainties associated with the development and commercialization of our potential 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 clinical trials for our PharmacoSurgery programs;
- costs related to manufacturing services;
- whether the hiring of a number of new employees to support our continued growth during this period will occur at salary levels consistent with our estimates;
- the scope, rate of progress, results and costs of our preclinical testing, clinical trials and other research and development activities for additional potential products;
- 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 potential products;
- market acceptance of our approved products, should they gain approval;
- the costs of commercialization activities, including product manufacturing, marketing, sales and distribution;
- the number and characteristics of potential products that we pursue;

the cost of establishing clinical and commercial supplies of our products;

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- 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;

- our degree of success in commercializing OMS302, OMS103HP and our other potential products;

- the extent to which we draw down funds under our committed equity line financing facility with Azimuth or otherwise access the capital markets; 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 continuing operating losses to result in an increasing total amount of cash used in operations over the next several years. To the extent our capital resources are insufficient 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. Except for our committed equity line financing facility with Azimuth, we currently do not have any commitments for future external equity or debt funding. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. In addition, any future equity funding will dilute the ownership of our equity investors.

Contractual Obligations and Commitments

There have been no significant changes during the six months ended June 30, 2012 to the items that we disclosed as our contractual obligations and commitments in our Form 10-K for the year ended December 31, 2011, except as follows:

On January 27, 2012, we entered into a lease with BMR-201 Elliott Avenue LLC for approximately 64,500 square feet of office and laboratory space. The term of the lease is 15 years with two options to extend the lease term, each by five years. The expected lease term commencement date is October 1, 2012. The annual base rent due under the lease is $0 for the first year, $2.5 million for the second year, $3.2 million for the third year and will increase by 2.5% each year thereafter, with an aggregate rent payable over the initial term of $51.1 million. We will also be responsible for paying our proportionate share of utilities, taxes, insurance and maintenance as well as a property management fee. The lease required us to provide the landlord with $563,000 as a security deposit, which is recorded as restricted cash on our balance sheet as of June 30, 2012. Additionally, the landlord has agreed to reimburse us for up to $650,000 in expenses incurred by us in connection with the leased premises, and on March 30, 2012 the landlord paid us a $3.0 million cash lease incentive.

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

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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.

We believe the following to be our critical accounting policies because they are both important to the portrayal of our financial condition and results of operations and they require critical judgment by management and estimates about matters that are uncertain:

- revenue recognition;
- research and development expenses, primarily clinical trial expenses; and
- stock-based compensation.

If actual results or events differ materially from those contemplated by us in making these estimates, our reported financial condition and results of operations for future periods could be materially affected.

Revenue Recognition

Our revenue is derived from grant funding from third parties and revenue recognized in connection with funding from Vulcan and LSDF for our GPCR program. We recognize revenue when the related qualified research and development expenses are incurred or services are provided up to the limit of the approved funding amounts.

The accounting standards for revenue provide a framework for accounting for revenue arrangements. A variety of factors are considered in determining the appropriate method of revenue recognition under these arrangements, such as whether the various elements can be considered separate units of accounting, whether there is objective and reliable evidence of fair value for these elements and whether there is a separate earnings process associated with a particular element of an agreement.

Research and Development Expenses

Research and development expenses are comprised primarily of employee and consultant-related expenses, which include salaries and benefits; external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, CROs and clinical trial sites; 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; third-party supplier expenses, including laboratory and other supplies; and payments to collaborators and licensors. Clinical trial expenses for investigational sites require certain estimates. We estimate these costs based on a cost per patient that varies depending on the clinical trial site. As actual costs become known to us, we adjust our estimates; these changes in estimates may result in understated or overstated expenses at a given point in time. Internal and third-party research and development expenses are expensed as incurred.

Stock-Based Compensation

Stock-based compensation cost is estimated at the grant date based on the award s fair value and is recognized on the straight-line method as expense over the requisite service period, which is generally the vesting period. Compensation cost for all stock-based awards is measured at fair value as of the grant date. The fair value of our stock options is calculated using the Black-Scholes option-valuation model. The Black-Scholes model requires the input of various subjective assumptions, including stock price volatility and expected option life. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense for new awards may differ materially in the future from that recorded in the current period.

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As stock-based compensation expense is based on options ultimately expected to vest, the expense has been reduced for estimated forfeitures. We estimate forfeitures based on our historical experience; separate groups of employees that have similar historical forfeiture behavior are considered separately for expense recognition.

Stock options granted to non-employees are accounted for using the fair-value approach. The fair value of non-employee option grants are estimated using the Black-Scholes option-pricing model and are re-measured over the vesting term as earned. The estimated fair value is charged to expense over the applicable service period.

Recent Accounting Pronouncements

In June 2011, FASB issued an Accounting Standards Update, or ASU, related to the presentation of comprehensive income which requires companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of changes in shareholders equity. The standard does not change the items that must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. This standard, which must be applied retroactively, was effective for interim and annual periods beginning after December 15, 2011. We adopted these standards on January 1, 2012, and have presented a combined statement of operations and comprehensive loss in our accompanying financial statements.

Off-Balance Sheet Arrangements

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

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 securities of high credit quality. As of June 30, 2012, we had cash, cash equivalents and short-term investments of $7.3 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 June 30, 2012. 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 June 30, 2012, 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.

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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

In December 2008, our former chief financial officer, Richard J. Klein, used our Whistleblower Policy procedures to report to the chairman of our audit committee that we had submitted grant reimbursement claims 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 January 2009, we terminated Mr. Klein s employment for reasons other than this incident. Mr. Klein alleged that he was wrongfully terminated and claimed the termination was retaliatory. We subsequently voluntarily reported to the NIH Mr. Klein s whistleblower report and the audit committee findings.

On September 21, 2009, Mr. Klein filed a lawsuit against us and some of our current and former directors in the United States District Court for the Western District of Washington, or WDWA, alleging, among other things, that we violated the Federal False Claims Act, wrongfully discharged his employment in violation of public policy and defamed him. Mr. Klein seeks, among other things, double damages in an amount to be proven at trial, actual litigation expenses, damages for loss of past and future earnings and his reasonable attorneys fees. On October 4, 2009, we filed with the court our amended answer to Mr. Klein s allegations, generally denying his claims and bringing counterclaims against Mr. Klein for breach of contract, misappropriation of trade secrets and breach of fiduciary duty. Mr. Klein filed an answer with the court generally denying our counterclaims. On January 8, 2010, the court dismissed all of our non-executive directors from the case with prejudice, and on July 27, 2010, Mr. Klein withdrew his defamation claim. On December 8, 2010, Mr. Klein was granted leave to amend his complaint to add qui tam claims asserted on behalf of the U.S. government under the Federal False Claims Act. The qui tam claims were based on the same NIH grant that was the subject of Mr. Klein s whistleblower report and related to NIH grants totaling $1.3 million. Mr. Klein seeks on behalf of the U.S. government and himself an award of civil penalties, treble damages and fees and costs. On October 17, 2011, the U.S. government filed a notice of its election to decline intervention in the qui tam claims, but this election does not prevent Mr. Klein from continuing these claims or his other claims and does not affect our claims against Mr. Klein. On March 13, 2012, the WDWA issued an order granting our motion to dismiss the majority of the qui tam claims for failing to meet statutory requirements, leaving pending only the qui tam claims related (1) to our alleged obligations stemming from $164,000 of grant funds drawn down by nura prior to our acquisition of nura in 2006 and (2) to timekeeping allegations regarding an NIH grant. We are vigorously defending ourselves against Mr. Klein s claims and seek, among other things, our attorneys fees and costs incurred in defending this action. Although we deny Mr. Klein s allegations and believe that we have meritorious defenses to his remaining claims, neither the outcome of the litigation nor the amount and range of potential damages or exposure associated with the litigation can be assessed with certainty.

Costs associated with defense of the lawsuit filed by Mr. Klein have to date been paid in part, subject to a reservation of rights by CCIC, which was the carrier for our Directors, Officers and Corporate Liability Insurance Coverage that was in place at the time Mr. Klein s employment with us was terminated. We have been and will continue to pay the remaining portion of the costs of defending the claims raised by Mr. Klein. On February 21, 2012, CCIC filed a complaint for a declaratory judgment against us, our chief executive officer and Mr. Klein in the WDWA, seeking a declaration that CCIC owes no duty to indemnify or defend us or our chief executive officer against the allegations raised by Mr. Klein. On May 10, 2012, we 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. We expect that CCIC will continue to pay a portion of the defense costs related to the qui tam claims in this lawsuit while these matters are pending. We intend to defend the declaratory judgment action and to pursue our counterclaims, vigorously. 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 pay our defense costs related to the lawsuit filed by Mr. Klein.

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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 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, 2011.

Risks Related to Our Potential Products, Programs and Operations

Our success may largely depend on the success of our co-lead PharmacoSurgery potential products, OMS302 and OMS103HP, and we cannot be certain that either of them will receive regulatory approval or be successfully commercialized. If we are unable to commercialize OMS302 or OMS103HP, or experience significant delays in doing so, our business may be materially harmed.

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 potential products OMS302 for use during ILR procedures and OMS103HP for use during arthroscopic partial meniscectomy surgery. We have not yet obtained regulatory approval to market either of these potential products for any indication in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize either of these products successfully.

We are conducting a Phase 3 clinical program that is evaluating OMS302 in patients undergoing ILR procedures. We expect this clinical program to consist of two trials that will enroll both cataract surgery and refractive lens exchange patients. In the first Phase 3 clinical trial, which we completed in March 2012, OMS302 achieved the primary endpoint of maintenance of intraoperative mydriasis. We expect to receive data from the second Phase 3 clinical trial during the second half of 2012. We can provide no assurance that the data from the second clinical trial will demonstrate a drug effect or that the trial will meet its co-primary endpoints maintenance of intraoperative mydriasis and reduction of ocular pain in the early postoperative period or that additional trials will not be required by regulatory authorities. If the data from the second Phase 3 trial do not demonstrate a drug effect or if the trial fails to meet both of its co-primary endpoints, our stock price may decline significantly and we may terminate any further development activities in the OMS302 program. Further, if we cannot complete the second clinical trial of OMS302 in our anticipated time frame, we may be significantly delayed in seeking, or be unable to seek, marketing approval of OMS302.

In addition, we are conducting a Phase 3 clinical program evaluating OMS103HP in patients undergoing arthroscopic partial meniscectomy surgery. This clinical program is planned to consist of two trials. We expect to receive data from the first trial in the second half of 2012. We are preparing for discussions with European regulatory authorities regarding the second Phase 3 clinical trial and, assuming sufficient resources, plan to begin that trial following completion of those discussions. OMS103HP demonstrated a drug effect in an earlier Phase 2 clinical trial in patients undergoing partial meniscectomy; however, we can provide no assurance that data from the ongoing Phase 3 meniscectomy program will demonstrate a drug effect or that the trials will meet the pre-specified efficacy endpoints or that additional trials will not be required by regulatory authorities. Also, we can provide no assurances that we will have sufficient resources to conduct the second clinical trial on schedule or at all. If we are delayed or unable to commence and complete the second clinical trial, we may be significantly delayed in seeking, or be unable to seek, marketing approval of OMS103HP.

In the first quarter of 2011, we announced that OMS103HP failed to meet pre-specified efficacy endpoints in a Phase 3 clinical program in patients undergoing arthroscopic ACL reconstruction surgery. Although we believe that data

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from a prior Phase 1/Phase 2 clinical trial of OMS103HP in ACL reconstruction show a drug effect in that indication, we were unable to draw any conclusions about its effect in the Phase 3 program due to confounding factors. We have no plans to conduct additional ACL reconstruction trials at this time.

We expect to incur significant clinical development and commercialization costs related to OMS302 and OMS103HP. If the resulting data for one or both of these potential products are not positive or if we are delayed or are unable to begin or complete the clinical trials, our business and prospects could be harmed materially and the trading price of our stock could decline significantly. Even if the data are positive for either of our co-lead potential products, the FDA and other regulatory authorities may decide that our clinical trials or data are insufficient for approval of these potential products and require additional preclinical, clinical or other studies. If these potential products do not subsequently receive regulatory approval or if approval is delayed beyond our expectations, or if we are unable to commercialize either product successfully, we may not be able to generate revenue, become profitable, fund the development of our other potential products or preclinical development programs or continue our operations.

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

Both before and after approval of our potential products, we, our potential 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.

Our potential products cannot be marketed in the United States without FDA approval, and can only be marketed for the indications, if any, for which they may be approved. The FDA has not approved any of our potential products for sale in the United States. All of our potential 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 potential products and require additional preclinical, clinical or other studies. As we develop our potential 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 those of our potential products consisting 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 potential 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 potential 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

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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.

We have not yet conducted a clinical trial designed to demonstrate the efficacy of OMS201 and, if we elect to conduct additional clinical trials evaluating OMS201, can provide no assurances that any of them will demonstrate efficacy.

Our success could also depend on the successful commercialization of our third PharmacoSurgery potential product, OMS201, for use during urological procedures. We have not obtained regulatory approval to market OMS201 for any indication in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize OMS201 successfully.

In the fourth quarter of 2010 we completed a successful Phase 1/Phase 2 clinical trial evaluating OMS201 in patients undergoing ureteroscopy for removal of ureteral or renal stones. This trial was designed to evaluate the safety and systemic absorption of two sequentially higher doses of OMS201, but the trial was not powered to assess efficacy. We have not yet conducted a clinical trial designed to demonstrate the efficacy of OMS201, we may not have the resources to conduct further clinical trials of OMS201 and can provide no assurances that, if such trials are performed, OMS201 will demonstrate efficacy. If we elect to conduct one or more additional clinical trials of OMS201, we will incur significant development costs and there can be no assurance that data from any subsequent clinical trials will be positive and, even if the data are positive, the FDA may decide that our clinical trials or data are insufficient for marketing approval and require additional preclinical, clinical or other studies. If OMS201 does not receive regulatory approval, or if it is not successfully commercialized, we may not be able to generate revenue, become profitable, fund the development of our other potential products or our preclinical programs or continue our operations.

If our clinical trials are delayed, we may be unable to develop our potential 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 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;

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- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials; or

- the placement of a clinical hold on a trial.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities 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, or 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 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 potential 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.

Our existing and future potential products, including our co-lead potential 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 potential 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;

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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 operations performed according to the market data obtained from industry sources. 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 will be significantly harmed.

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 $28.5 million, $29.3 million and $21.1 million for the years ended December 31, 2011, 2010 and 2009, respectively. As of June 30, 2012, we had an accumulated deficit of approximately $193.6 million. We expect to incur additional losses for at least the next several years and cannot be certain that we will ever achieve profitability, and we do not anticipate generating revenue from the sale of our products until 2014 at the earliest. 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 potential 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 potential 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:

complete the Phase 3 clinical program of OMS302 for use in ILR procedures;

complete the Phase 3 clinical program of OMS103HP for use in arthroscopic partial meniscectomy surgery;

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

scale-up and produce clinical and commercial supplies of products, and conduct clinical studies for our potential products, including for our PDE10, PDE7, MASP-2 and Plasmin programs;

initiate, conduct and complete the next clinical trials of OMS201 for use in urological procedures;

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 potential products; and

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make milestone payments to our collaborators;

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

If we do not raise additional capital, we may be unable to complete all of the clinical trials in our Phase 3 clinical programs for OMS302 and OMS103HP, which would prevent us from seeking marketing approval and generating sales revenue for one or both of those potential 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. Furthermore, we may need to raise additional capital to advance one or more of our preclinical programs into clinical development. If we are unable to raise sufficient capital to complete the clinical development of OMS302 or OMS103HP or advance one or more of our preclinical development programs into the clinic, our business and prospects could be harmed and our stock price could decline significantly.

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 of a loan and security agreement with Oxford, pursuant to which we owed $16.9 million in principal and interest as of June 30, 2012. 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 and security 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 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.

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 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 we are acquired in a change of control, the acquiring party will be required to assume our rights and obligations under the Vulcan and LSDF agreements. A party that wants to acquire us through a change of control may also be less inclined to do so or not be willing to pay as much to acquire us because of the Vulcan and LSDF agreements.

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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 restricts 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 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 potential 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. Our reliance on these third parties does not relieve us of responsibility for ensuring compliance with FDA 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 potential products.

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.

We do not have a sales and marketing organization, and 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 obtain access to or persuade 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

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

We do not intend to manufacture our potential 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 potential 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 potential products could materially harm our business and prospects.

If the contract manufacturers that we rely on experience difficulties with manufacturing our potential 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 potential 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 potential 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 potential 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 potential 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 potential 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 potential 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.

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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 potential products.

We must purchase from third-party suppliers the ingredients necessary for our contract manufacturers to produce our PharmacoSurgery potential 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 potential products would be delayed, significantly impacting our ability to develop our potential products, which would materially affect our ability to generate revenue from the sale of our products.

We may need licenses for active ingredients from third parties so that we can develop and commercialize some potential 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 potential products from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these potential 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.

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 Biotech ApS. 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 Biotech ApS up to $6.9 million upon the achievement of certain events related to a MASP-2 product, such as the filing of an Investigational New Drug application with the FDA, initiation of clinical trials, receipt of marketing approval and reaching specified sales milestones. Our ability to continue development and commercialization of potential 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 potential 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. We do not currently have agreements in place with manufacturers of biologics to manufacture clinical or commercial quantities of drug product for our MASP-2 or Plasmin programs and cannot be certain that such agreements could be entered into on commercially reasonable terms, if at all. There are only a limited number of manufacturers of biologic drug products. If we are unable to obtain clinical supplies of drug product for one of these programs, clinical trials or the development of any such potential 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 potential products that are suitable for clinical trials or that can be successfully commercialized or generate revenue through partnerships.

Any potential products from our preclinical programs, including our PDE10, 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 potential products that are suitable for clinical testing. For example, we have not yet generated any potential 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 potential products that successfully complete preclinical or clinical testing. If we are unable to develop potential products, potential corporate partners may be unwilling to enter into partnership agreements with us. We also cannot be certain that any potential 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 potential products, we may expend our limited resources to pursue a particular product or products and fail to capitalize on potential 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 potential products that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other potential 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

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we do not accurately evaluate the commercial potential or target market for a particular potential product, we may relinquish valuable rights to that potential 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.

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.

Our issued PharmacoSurgery patents that are directed to OMS302 and OMS103HP have terms that will expire as late as July 30, 2023 for OMS302 and September 24, 2022 for OMS103HP. If our pending PharmacoSurgery applications issue as patents, the expiration dates of those patents will be August 4, 2032 for OMS103HP and March 17, 2026 for OMS201, not taking into account any extensions due to potential adjustment of patent terms resulting from USPTO delays. We intend to file additional patent applications directed to OMS302 which, if issued, are expected to provide patent terms ending 2033 or later. We cannot assure you that any of these 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;

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- 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.

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

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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 potential 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.

We may experience disruptions to our business in connection with moving our offices and laboratory into a new facility during 2012.

In late 2012, we intend to move all of our operations, including our laboratory and vivarium, to a new building. Under our lease, the landlord is responsible for building a laboratory and vivarium in this new facility to our specifications. We can provide no assurances that the landlord will be able to construct a laboratory and vivarium to our specifications by the time that we are required to vacate our current laboratory and vivarium space, or at all. Further, even if the new facility meets our specifications, after moving our laboratory and vivarium into this building we may discover problems that disrupt our research efforts. Any of these problems could substantially damage, disrupt or delay our research and development efforts, require us to find a new facility for our laboratory and vivarium that may not be available on commercially reasonable terms or at all, and materially harm one or more of our development programs and our business and prospects.

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

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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, interim chief financial officer, treasurer and chairman of the board of directors. 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.

Our former chief financial officer has filed a lawsuit against us and our current and former directors, the defense of which has and will continue to consume our time and resources and could harm our reputation and the reputations of our current and former directors, materially negatively affect our financial position and cause our stock price to decline.

In December 2008, our former chief financial officer, Richard J. Klein, used our Whistleblower Policy procedures to report to the chairman of our audit committee that we had submitted grant reimbursement claims 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 January 2009, we terminated Mr. Klein s employment for reasons other than this incident. Mr. Klein alleged that he was wrongfully terminated and claimed the termination was retaliatory. We subsequently voluntarily reported to the NIH Mr. Klein s whistleblower report and the audit committee findings.

On September 21, 2009, Mr. Klein filed a lawsuit against us and some of our current and former directors in the WDWA alleging, among other things, that we violated the Federal False Claims Act, wrongfully discharged his employment in violation of public policy and defamed him. Mr. Klein seeks, among other things, double damages in an amount to be proven at trial, actual litigation expenses, damages for loss of past and future earnings and his reasonable attorneys fees. On January 8, 2010, the court dismissed all of our non-executive directors from the case with prejudice, and on July 27, 2010 Mr. Klein withdrew his defamation claim. On December 8, 2010, Mr. Klein was granted leave to amend his complaint to add qui tam claims asserted on behalf of the U.S. government under the Federal False Claims Act.

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The qui tam claims were based on the same NIH grant that was the subject of Mr. Klein s whistleblower report and related NIH grants totaling $1.3 million. Mr. Klein seeks on behalf of the U.S. government and himself an award of civil penalties, treble damages and attorneys fees and costs. On October 17, 2011, the U.S. government filed a notice of its election to decline intervention in the qui tam claims, but this election does not prevent Mr. Klein from continuing these claims or his other claims and does not affect our claims against Mr. Klein. On March 13, 2012, the WDWA issued an order granting our motion to dismiss the majority of the qui tam claims for failing to meet statutory requirements, leaving pending only the qui tam claims related (1) to our alleged obligations stemming from $164,000 of grant funds drawn down by nura prior to our acquisition of nura in 2006 and (2) to timekeeping allegations regarding an NIH grant. We are vigorously defending ourselves against Mr. Klein s claims and seek, among other things, our attorneys fees and costs incurred in defending this action. Although we deny Mr. Klein s allegations and believe that we have meritorious defenses to his remaining claims, neither the outcome of the litigation nor the amount and range of potential damages or exposure associated with the litigation can be assessed with certainty. Further, defending this lawsuit has already consumed and will continue to consume our time and resources and could, depending on the outcome, harm our reputation and the reputations of our current and former directors, and materially negatively affect our financial position and cause our stock price to decline.

Costs associated with the defense of the lawsuit filed by Mr. Klein have to date been paid in part, subject to a reservation of rights, by CCIC, which was the carrier for our Directors, Officers and Corporate Liability Insurance Coverage that was in place at the time Mr. Klein s employment with us was terminated. We have been and will continue to pay the remaining portion of the costs of defending the claims raised by Mr. Klein. On February 21, 2012, CCIC filed a complaint for a declaratory judgment against us, our chief executive officer and Mr. Klein in the WDWA, seeking a declaration that CCIC owes no duty to indemnify or defend us or our chief executive officer against the allegations raised by Mr. Klein. We expect that CCIC will continue to pay a portion of the defense costs related to the qui tam claims in this lawsuit while these matters are pending. We intend to defend the declaratory judgment action vigorously. While we can provide no assurances regarding the outcome of the litigation with CCIC, we believe CCIC is required under the insurance policy to pay our defense costs related to the lawsuit filed by Mr. Klein.

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.

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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.

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 potential 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 potential products, that reach the market before our products, or that otherwise negatively affect the market, we may not achieve commercial success. For example, we are preparing to conduct a Phase 1 clinical trial evaluating our proprietary PDE10 inhibitor for use in the treatment of cognitive disorders, including schizophrenia and Huntington s disease. Other pharmaceutical companies, many with significantly greater resources than we have, are also developing PDE10 inhibitors and these companies may be further along in development. 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 our PDE10 inhibitor under development 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 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

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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.

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.

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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 potential 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 potential products have 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 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.

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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.

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 June 30, 2012, our stock traded as high as $13.45 per share and as low as $3.16 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:

- results from our clinical development programs, including the data from our ongoing Phase 3 clinical trials evaluating OMS302 and OMS103HP that we expect to announce during the second half of 2012;
- FDA or international regulatory actions, including failure to receive regulatory approval for any of our potential products;
- announcements regarding the progress of 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 $20.0 million debt facility with Oxford, pursuant to which our indebtedness for outstanding principal and interest was $16.9 million as of June 30, 2012;
- 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.

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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 potential 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.

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, except for our committed equity line financing facility described below, we have no commitments for additional capital and cannot be certain that it will be available 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 committed equity line financing facility, 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 potential 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 potential 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 potential 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 our committed equity line financing facility, our existing shareholders will experience immediate dilution and, as a result, our stock price may go down.

In May 2011, we entered into a committed equity line financing facility, or financing arrangement, under which we may sell up to $40.0 million of our common stock to Azimuth over a 24-month period subject to a maximum of 4,427,562 shares of our common stock. If we elect to use the financing arrangement, the sale of shares of our common stock to Azimuth will have a dilutive impact on our existing shareholders. Azimuth may resell some or all of the shares we issue to it pursuant to the financing arrangement and such sales could cause the market price of our common stock to decline significantly with advances under the financing arrangement. To the extent of any such decline, any subsequent advances would require us to issue a greater number of shares of common stock to Azimuth in exchange for each dollar of the advance. Under these circumstances, our existing shareholders would experience greater dilution and the total amount of financing that we will be able to raise pursuant to the financing arrangement could be significantly lower than $40.0 million. Although Azimuth is precluded from short sales of shares acquired pursuant to advances under the financing arrangement, the sale of our common stock under the financing arrangement could encourage short sales by third parties, which could contribute to the further decline of our stock price.

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

Approximately 6.9 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 and security agreement with Oxford dated October 21, 2010, 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.

ITEM 6. EXHIBITS

Exhibit Number	Description
10.1*	Underwriting Agreement, dated June 27, 2012, among the Registrant and the several underwriters party thereto
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

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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 June 28, 2012 (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.

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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: August 7, 2012

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