

OMEROS CORP  
Form 10-Q  
November 08, 2011  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

September 30, 2011 For the quarterly period ended September 30, 2011

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)

Edgar Filing: OMEROS CORP - Form 10-Q

**Washington**  
(State or other jurisdiction of  
incorporation or organization)  
**1420 Fifth Avenue, Suite 2600**  
**Seattle, Washington**  
(Address of principal executive offices)  
**(206) 676-5000**  
(Registrant's telephone number, including area code)

**91-1663741**  
(I.R.S. Employer  
Identification Number)  
**98101**  
(Zip 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  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  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   
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

As of November 3, 2011, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 22,358,162.

---

**Table of Contents**

**OMEROS CORPORATION**

**FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2011**

**INDEX**

	<b>Page</b>
<b><u>Part I Financial Information</u></b>	<b>3</b>
Item 1. <u>Financial Statements</u>	3
<u>Consolidated Balance Sheets as of September 30, 2011 and December 31, 2010</u>	3
<u>Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2011 and 2010 and for the period from June 16, 1994 (inception) through September 30, 2011</u>	4
<u>Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2011 and 2010 and for the period from June 16, 1994 (inception) through September 30, 2011</u>	5
<u>Notes to Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	24
Item 4. <u>Controls and Procedures</u>	25
<b><u>Part II Other Information</u></b>	<b>25</b>
Item 1. <u>Legal Proceedings</u>	25
Item 1A. <u>Risk Factors</u>	26
Item 6. <u>Exhibits</u>	45
<u>Signatures</u>	46

**Table of Contents****PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****OMEROS CORPORATION****(A Development-Stage Company)****CONSOLIDATED BALANCE SHEETS****(In thousands, except share and per share data)**

	September 30, 2011 (unaudited)	December 31, 2010
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,888	\$ 3,278
Short-term investments	27,965	38,715
Grant and other receivables	776	1,479
Prepaid expenses and other current assets	210	282
<b>Total current assets</b>	<b>33,839</b>	<b>43,754</b>
Property and equipment, net	833	1,622
Restricted cash	193	193
Other assets	119	135
<b>Total assets</b>	<b>\$ 34,984</b>	<b>\$ 45,704</b>
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,647	\$ 2,398
Accrued expenses	2,611	4,567
Deferred revenue	6,282	8,014
Current portion of notes payable	5,275	395
<b>Total current liabilities</b>	<b>15,815</b>	<b>15,374</b>
Notes payable, less current portion	15,092	9,860
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, par value \$0.01 per share:		
Authorized shares 20,000,000;		
Issued and outstanding none		
Common stock, par value \$0.01 per share:		
Authorized shares 150,000,000 at September 30, 2011 (unaudited) and December 31, 2010;		
Issued and outstanding shares 22,313,788 and 21,920,836 at September 30, 2011 (unaudited) and December 31, 2010, respectively	223	219
Additional paid-in capital	169,786	167,838
Deficit accumulated during the development stage	(165,932)	(147,587)
<b>Total shareholders' equity</b>	<b>4,077</b>	<b>20,470</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 34,984</b>	<b>\$ 45,704</b>

Edgar Filing: OMEROS CORP - Form 10-Q

See notes to Consolidated Financial Statements

**Table of Contents**

**OMEROS CORPORATION**  
**(A Development-Stage Company)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(In thousands, except share and per share data)**  
**(unaudited)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>		<b>Period from</b>
	<b>September 30,</b>		<b>September 30,</b>		<b>June 16,</b>
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>	<b>1994</b>
					<b>(Inception)</b>
					<b>through</b>
	<b>September 30,</b>		<b>September 30,</b>		<b>September 30,</b>
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>	<b>2011</b>
Revenue	\$ 987	\$ 254	\$ 3,381	\$ 1,129	\$ 10,323
Operating expenses:					
Research and development	5,321	5,316	14,823	16,518	117,451
Acquired in-process research and development					10,891
General and administrative	1,830	2,428	6,121	6,160	52,623
Total operating expenses	7,151	7,744	20,944	22,678	180,965
Loss from operations	(6,164)	(7,490)	(17,563)	(21,549)	(170,642)
Investment income	9	108	40	146	5,584
Interest expense	(528)	(362)	(1,348)	(1,223)	(5,714)
Loss on extinguishment of debt					(296)
Other income, net	171	189	526	606	5,136
Net loss	\$ (6,512)	\$ (7,555)	\$ (18,345)	\$ (22,020)	\$ (165,932)
Basic and diluted net loss per common share	\$ (0.29)	\$ (0.35)	\$ (0.83)	\$ (1.03)	
Weighted-average shares used to compute basic and diluted net loss per common share	22,246,430	21,487,621	22,156,883	21,387,577	

See notes to Consolidated Financial Statements

**Table of Contents**

**OMEROS CORPORATION**  
**(A Development-Stage Company)**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(In thousands)**  
**(unaudited)**

	Nine Months Ended September 30,		Period from June 16, 1994 (Inception) through September 30, 2011
	2011	2010	
<b>Operating activities</b>			
Net loss	\$ (18,345)	\$ (22,020)	\$ (165,932)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	336	408	2,810
Stock-based compensation expense	1,472	1,574	15,302
Change in fair value of preferred stock warrant values and success fee liability			(253)
Non-cash interest expense	247	134	729
Loss on extinguishment of debt			296
Other than temporary impairment and loss on sale of investment securities		33	275
Write-off of deferred public offering costs			1,948
Acquired in-process research and development			10,891
Changes in operating assets and liabilities, net of nura acquisition in 2006:			
Grant and other receivables	2,318	(252)	2,139
Prepaid expenses and other current and noncurrent assets	94	(60)	(123)
Deferred public offering costs			(1,948)
Accounts payable and accrued expenses	(2,735)	(601)	3,592
Deferred revenue	(1,694)	(340)	9,160
Net cash used in operating activities	(18,307)	(21,124)	(121,114)
<b>Investing activities</b>			
Purchases of property and equipment	(1,200)	(759)	(4,079)
Purchase of Patobios intellectual property assets			(7,631)
Reimbursement of Patobios intellectual property assets			7,631
Purchases of investments	(9,000)	(38,765)	(214,869)
Proceeds from the sale of investments	19,750	66,173	141,639
Proceeds from the maturities of investments		322	45,026
Cash paid for acquisition of nura, net of cash acquired of \$87			(212)
Net cash provided by investing activities	9,550	26,971	(32,495)
<b>Financing activities</b>			
Proceeds from issuance of common stock upon initial public offering, net of offering costs of \$6,388			61,812
Proceeds from borrowings under note payable, net of loan origination costs and prepayment penalty	9,942		36,612
Payments on notes payable	(55)	(4,125)	(19,636)
Proceeds from issuance of common stock upon exercise of stock options	480	254	1,449

Edgar Filing: OMEROS CORP - Form 10-Q

Proceeds from issuance of convertible preferred stock, net of issuance costs			78,234
Other, net			26
<b>Net cash provided by (used in) financing activities</b>	<b>10,367</b>	<b>(3,871)</b>	<b>158,497</b>
Net increase in cash and cash equivalents	1,610	1,976	4,888
Cash and cash equivalents at beginning of period	3,278	820	
Cash and cash equivalents at end of period	\$ 4,888	\$ 2,796	\$ 4,888
<b>Supplemental cash flow information</b>			
Cash paid for interest	\$ 1,031	\$ 1,055	\$ 4,856
Issuance of common stock to Patobios in connection with purchase of intellectual property assets	\$	\$	\$ 3,146
Reduction of equipment cost basis due to assets purchased with grant funding	\$ 1,653	\$	\$ 1,653
Issuance of warrants	\$	\$	\$ 1,235
Preferred stock and common stock issued in connection with nura acquisition	\$	\$	\$ 14,070
Property acquired under capital lease	\$	\$ 201	\$ 201

See notes to Consolidated Financial Statements



---

**Table of Contents**

**OMEROS CORPORATION**

**(A Development-Stage Company)**

**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. We are a development-stage company. 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 September 30, 2011 and for the three and nine months ended September 30, 2011 and 2010, includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The December 31, 2010 balance sheet reflects a \$500,000 increase and decrease to long-term notes payable and accrued expenses, respectively, to conform to the current presentation. The consolidated balance sheet at December 31, 2010 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, 2010.

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. The acquisition of nura was accounted for as a purchase of assets, and the results of nura have been included in our results since August 11, 2006.

*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.

*Recent Accounting Pronouncements*

In 2009, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update, or ASU, related to revenue recognition that amends the previous guidance on arrangements with multiple deliverables. This guidance provides principles and application guidance on whether multiple deliverables exist, how the arrangements should be separated, and how the consideration should be allocated. It also clarifies the method to allocate revenue in an arrangement using the estimated selling price. We adopted this standard effective January 1, 2011 and it had no impact on our financial statements.

In January 2010, FASB issued guidance that requires reporting entities to make new disclosures about recurring or nonrecurring fair-value measurements, including significant transfers into and out of Level 1 and Level 2 fair-value measurements and information on purchases, sales, issuances and settlements on a gross basis in the reconciliation of Level 3 fair-value measurements. The guidance pertaining to Level 1 and Level 2 measurements was effective for the year



**Table of Contents**

ended December 31, 2010. The adoption of this guidance did not have a material impact on our consolidated financial statements. The guidance pertaining to Level 3 reconciliation disclosures will be effective for the year ending December 31, 2011. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In 2010, FASB issued an ASU related to revenue recognition that applies to arrangements with milestones relating to research or development deliverables. This guidance provides criteria that must be met to recognize consideration that is contingent upon achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. We adopted this standard effective January 1, 2011 and it had no impact on our financial statements.

In June 2011, FASB issued an ASU related to the presentation of comprehensive income that will require 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, is effective for interim and annual periods beginning after December 15, 2011. We will adopt these standards on January 1, 2012. As this update impacts presentation only, it will have no effect on our financial condition or results of operations.

**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 both the treasury-stock and the as if-converted methods.

The basic and diluted net loss per share amounts for the three and nine months ended September 30, 2011 and 2010 were computed based on the shares of common stock outstanding during the respective periods. The following table presents the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<b>Historical</b>				
<b>Numerator:</b>				
Net loss	\$ (6,512)	\$ (7,555)	\$ (18,345)	\$ (22,020)
<b>Denominator:</b>				
Denominator for basic and diluted net loss per share	22,246,430	21,487,621	22,156,883	21,387,577
Basic and diluted net loss per common share	\$ (0.29)	\$ (0.35)	\$ (0.83)	\$ (1.03)

Historical outstanding dilutive securities not included in diluted loss per common share calculation:

	September 30,	
	2011	2010
Outstanding options to purchase common stock	3,166,939	3,508,898
Warrants to purchase common stock	609,016	209,017
<b>Total</b>	<b>3,775,955</b>	<b>3,717,915</b>

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

## Edgar Filing: OMEROS CORP - Form 10-Q

Our investment portfolio is made up of cash and cash equivalents and available-for-sale money-market funds that are classified as short-term investments on the accompanying balance sheets. We did not own any securities with unrealized loss positions as of September 30, 2011 or December 31, 2010.

Our investment income consists primarily of interest income.

**Table of Contents****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 is as follows:

	Level 1	September 30, 2011 Level 2    Level 3 (in thousands)		Total
<b>Assets:</b>				
Money-market funds classified as cash equivalents and restricted cash	\$ 2,427	\$	\$	\$ 2,427
Money-market funds classified as short-term investments	27,965			27,965
Total	\$ 30,392	\$	\$	\$ 30,392

	Level 1	December 31, 2010 Level 2    Level 3 (in thousands)		Total
<b>Assets:</b>				
Money-market funds classified as cash equivalents and restricted cash	\$ 2,323	\$	\$	\$ 2,323
Money-market funds classified as short-term investments	38,715			38,715
Total	\$ 41,038	\$	\$	\$ 41,038

Cash of \$2.7 million and \$1.1 million was excluded from our fair-value hierarchy disclosure as of September 30, 2011 and December 31, 2010, respectively. Additionally, the fair-value hierarchy disclosure includes restricted cash of \$193,000 as of September 30, 2011 and December 31, 2010. There were no unrealized gains and losses associated with our short-term investments as of September 30, 2011 or December 31, 2010.

**Note 5 Certain Balance Sheet Accounts***Accrued Expenses*

Accrued expenses consisted of the following:

	September 30, 2011	December 31, 2010
	(in thousands)	
Clinical trials	\$ 818	\$ 2,548
Contract preclinical research and manufacturing Contract research	816	351

## Edgar Filing: OMEROS CORP - Form 10-Q

Employee compensation	342	974
Other accruals	635	694
Accrued expenses	\$ 2,611	\$ 4,567

### Note 6 Notes Payable

In October 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. In March 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.

---

**Table of Contents**

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. Included in these debt issuance costs is a one-time facility fee payment to Oxford of \$50,000. 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 and nine months ended September 30, 2011, total non-cash interest expense associated with our borrowings under the Tranche 1 and Tranche 2 notes includes amortization of the discount of \$77,000 and \$195,000, respectively, and amortization of debt issuance costs of \$19,000 and \$52,000, respectively.

**Note 7 Revenue**

We have received Small Business Innovative Research, or SBIR, grants from the National Institutes of Health since inception through September 30, 2011 totaling \$4.3 million. The grants support research and development of our product candidates. We recorded revenue related to these grants of \$49,000 and \$138,000 for the three months ended September 30, 2011 and 2010, respectively, and \$258,000 and \$748,000 for the nine months ended September 30, 2011 and 2010, respectively. As of September 30, 2011, \$603,000 of funding remained under these grants.

In December 2006, we entered into a funding agreement with The Stanley Medical Research Institute, or SMRI, to develop a proprietary PDE10 inhibitor product candidate for the treatment of schizophrenia. Under the agreement, we may receive grant and equity funding of up to \$9.0 million upon achievement of product development milestones through Phase 1 clinical trials, subject to our mutual agreement with SMRI. We hold the exclusive rights to the technology. In consideration for SMRI's grant funding, we will become obligated to pay SMRI royalties based on net income, as defined under the agreement, from commercial sales of a PDE10 inhibitor product, not to exceed a set multiple of total grant funding received. If a PDE10 inhibitor product candidate does not reach commercialization, we are not required to repay the grant funds. Through September 30, 2011, we have received a total of \$5.7 million from SMRI in the form of grant and equity funding. As of September 30, 2011, all grant amounts pertaining to this agreement previously recorded as deferred revenue in the accompanying balance sheet have been recognized as revenue. In 2007 and 2009, as consideration for the equity funding noted above, we sold an aggregate of 255,103 shares of Series E convertible preferred stock to SMRI, which were subsequently converted to common stock in connection with our initial public offering. We recognized revenue under the SMRI funding agreement of \$0 and \$119,000 for the three months ended September 30, 2011 and 2010, respectively, and \$227,000 and \$343,000 for the nine months ended September 30, 2011 and 2010, respectively.

In October 2010, we entered into a platform development funding agreement with Vulcan Inc. and its affiliate, which we refer to collectively as Vulcan, pursuant to which we received \$20.0 million for our G protein-coupled receptor, or GPCR, program 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 in October 2010, we entered into an agreement with the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or LSDF, under which we received a \$5.0 million grant award from LSDF that will be paid to us as reimbursement of expenses that we incur and for equipment purchases we make for our GPCR program. For the three and nine months ended September 30, 2011, we have recorded reductions to the Vulcan deferred revenue balance of \$505,000 and \$1.5 million, respectively, which includes \$491,000 and \$1.4 million recognized as revenue and \$14,000 and \$38,000 recorded as cost reductions to assets, respectively. As of September 30, 2011, \$6.3 million in deferred revenue pertaining to the Vulcan Agreement was recorded in the accompanying balance sheet. Under the LSDF agreement, for the three and nine months ended September 30, 2011, respectively, we recognized revenue of \$445,000 and \$1.5 million and have recorded cost reductions to assets of \$3,000 and \$1.6 million. As of September 30, 2011, we had incurred \$3.8 million of expenses reimbursable by LSDF under our grant award agreement. See additional discussion of the Vulcan and LSDF agreements under Note 8.

---

**Table of Contents****Note 8 Commitments and Contingencies**

In connection with our 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 September 30, 2011, the maximum amount of royalties payable by us is \$12.8 million. We have not paid any such royalties through September 30, 2011.

In February 2009, we entered into a patent assignment agreement with an individual whereby we acquired all intellectual property rights, including patent applications, related to peroxisome proliferators activated receptor gamma, or PPAR $\gamma$ , agonists for the treatment and prevention of addictions to substances of abuse, as well as other compulsive behaviors. No payments were made related to the technology acquisition. In February 2011, we amended the patent assignment agreement to include all intellectual property rights, including patent applications, related to dietary supplements that increase PPAR $\gamma$  activity. Under the agreement, we will be required to make payments of up to \$3.8 million in total, for both PPAR $\gamma$  agonists and dietary supplements that increase PPAR $\gamma$  activity, to the individual upon achievement of certain development events, such as the initiation of clinical trials and receipt of marketing approval. In addition, we are obligated to pay a low single-digit percentage royalty on any net sales of drug products that are covered by any patents that issue from the acquired patent application. We recorded no research and development expense under the patent assignment agreement during the three and nine months ended September 30, 2011 and 2010.

In March 2010, we entered into a license agreement with Daiichi-Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.), or Daiichi, pursuant to which we received an exclusive license to PDE7 inhibitors claimed in certain patents and pending patent applications owned by Daiichi for use in the treatment of movement disorders and other specified indications. In February 2011, we amended the agreement to include addiction and compulsive disorders in the field of use. Under the amended agreement, we agreed to make milestone payments to Daiichi 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 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 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. We recorded no research and development expense under this agreement during the three months ended September 30, 2011 and 2010, and \$13,000 and \$25,000 for the nine months ended September 30, 2011 and 2010, respectively.

In April 2010, we entered into an exclusive license agreement with Helion Biotech ApS, or Helion, pursuant to which we received a royalty bearing, worldwide exclusive license in and to all of Helion's intellectual property rights related to 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. We recorded no research and development expense under this agreement during the three months ended September 30, 2011 and 2010, and \$15,000 and \$529,000 for the nine months ended September 30, 2011 and 2010, respectively.

In September 2008, we entered into a technology option agreement with Patobios to evaluate and potentially acquire the intellectual property rights covering Patobios' GPCR technology. Under the terms of the agreement, as amended in November 2009, Patobios granted us an option to evaluate the technology over four option periods commencing September 2008 and continuing up to December 2010. Under the terms of the agreement, we had the exclusive option to acquire the intellectual property rights, including patents, covering Patobios' GPCR technology at any time during any of the option periods. We made a non-refundable payment of \$188,000 to Patobios following execution of the agreement for the first nine-month option period and a payment of \$471,000 for the second six-month option period, all of which was charged to research and development expense. As of December 31, 2009, the second option period was automatically extended until January 2010 at a cost to us of \$104,000 and we exercised our right to extend the third option period from



**Table of Contents**

January 2010 to June 2010 at a cost to us of \$516,000, which was recorded as research and development expense in 2009. In June 2010, we exercised our right to extend the fourth option period from July 2010 to December 2010 at a cost to us of \$487,000. In November 2010 we purchased the GPCR technology from Patobios for \$10.8 million, of which approximately \$7.6 million was paid in cash and \$3.2 million was paid in the form of 379,039 shares of our common stock. We have no future royalty, milestone, or other payment obligations to Patobios. As Vulcan funded the purchase of these assets, we have no cost basis in the assets acquired. We recognized research and development expense under the Patobios agreement of \$0 and \$497,000, for the three and nine months ended September 30, 2010, respectively.

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 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.

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

Under our agreement with LSDF, after LSDF receives \$25.0 million from us, any remaining amounts that would be payable by us to LSDF pursuant to the agreement will instead be paid to LSI. Our obligations with respect to LSI are limited to creating LSI's charter documents, incorporating LSI, selecting directors and applying for tax exempt status, all in consultation with LSDF. We have no other obligations, funding or otherwise, to LSI. The term of our agreement with LSDF expires on the six-month anniversary following the last date that we deliver a report related to our incurrence of grant-funded expenses described in the agreement, provided that certain obligations will survive the expiration of the term. The term of our payment obligations to LSDF is the same as that under our agreement with Vulcan. In addition, pursuant to our agreements with Vulcan and LSDF, we have agreed (1) to use commercially reasonable efforts to screen at least 75% of the currently known human Class A orphan GPCRs within 19 months from the date of the agreements, subject to possible extensions and (2) to commence a medicinal chemistry effort focused on developing a product candidate with respect to one orphan GPCR for which compounds were identified using the GPCR assay technology.

**Note 9 Shareholders Equity**

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. From time to time over the 24-month term, and in our sole discretion, we may present Azimuth with draw down notices requiring Azimuth to purchase a specified dollar amount of shares of our common stock, based on the volume-weighted average price per share on each of 10 consecutive trading days, or the draw down period, with the total dollar amount of each draw down subject to certain agreed-upon limitations based on the market price of our common stock at the time of the draw down. The purchase price for these shares equals the daily volume-weighted average price of our common stock on each date during the draw down period on which shares are purchased, less a discount ranging from 3.00% to 6.00%, based on a minimum price that we specify. In addition, in our sole discretion, but subject to certain limitations, we may require Azimuth to purchase a percentage of the daily trading volume of our common stock for each trading day during the draw down.

**Table of Contents**

period. 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 funds under this facility.

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

**Note 10 Stock-Based Compensation***Stock Options*

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

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

1,785,714 shares; and

such other amount as our board of directors may determine.

On January 1, 2011 in accordance with the 2008 Plan annual increase provisions, the authorized shares in the 2008 Plan increased by 1,096,041 shares. During the nine months ended September 30, 2011, the authorized shares in the 2008 Plan increased by an additional 8,242 shares as a result of the cancellation of options under the 1998 Plan. As of September 30, 2011, a total of 3,418,554 shares were reserved for issuance under the 2008 Plan.

A summary of stock option activity and related information follows:

	Options Outstanding	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance at December 31, 2010	3,589,292	\$ 3.09		
Granted	65,300	5.55		
Exercised	(392,952)	1.22		
Forfeited	(94,701)	6.13		
Balance at September 30, 2011	3,166,939	\$ 3.28	6.53	\$ 5,499,366
Exercisable at September 30, 2011	2,391,443	\$ 2.21	5.86	\$ 5,481,793

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 of September 30, 2011, we had approximately \$2.8 million of unrecognized compensation expense related to our unvested stock options. We expect to recognize this compensation expense over a weighted-average period of approximately 2.3 years.

**Table of Contents**

As stock-based compensation expense is based on options ultimately expected to vest, the expense has been reduced for estimated forfeitures. No options were granted to employees during the three months ended September 30, 2011, thus assumptions for the period were not updated. 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Weighted-average estimated fair value	N/A	\$4.97	\$3.65	\$4.22
<b>Weighted-average Assumptions:</b>				
Expected volatility	N/A	75%	81% -82%	75% -77%
Expected term (in years)	N/A	6.08	5.50	5.96
Risk-free interest rate	N/A	1.72%	1.88%	-2.50%
Expected dividend yield	N/A	0%	0%	0%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	(in thousands)			
Research and development	\$ 185	\$ 266	\$ 643	\$ 644
General and administrative	282	308	829	930
<b>Total</b>	<b>\$ 467</b>	<b>\$ 574</b>	<b>\$ 1,472</b>	<b>\$ 1,574</b>

In connection with the non-employee options, we recognized expense of \$5,000 and \$20,000 for the three months ended September 30, 2011 and 2010, respectively, and \$58,000 and \$72,000 for the nine months ended September 30, 2011 and 2010, respectively.

**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, 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 for purposes of these provisions. In some cases you can identify forward-looking statements by terms such as may, will, should, could, would, expect, plan, anticipate, believe, estimate, project, predict, and potential, and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding:*

*the impact of recent accounting pronouncements on our consolidated financial statements;*

*our ability to advance our PDE10 program through the completion of Phase 1 clinical trials with the funding we may receive from The Stanley Medical Research Institute;*

*our expectation that we will have data from the first Phase 3 clinical trial in our OMS103HP program in mid-year 2012;*

Edgar Filing: OMEROS CORP - Form 10-Q

*our expectation that we will have data from the first Phase 3 clinical trial in our OMS302 program in the first quarter of 2012;*

*our expectation that we will begin the second Phase 3 clinical trials in our OMS103HP and OMS302 programs following discussions with European regulatory authorities;*

## **Table of Contents**

*our expectations regarding the clinical benefits of our product candidates, including whether OMS103HP will be the first commercially available drug delivered directly to the surgical site to improve function following arthroscopic surgery;*

*our capability to continue high-throughput surrogate de-orphanization of orphan G protein-coupled receptors, or GPCRs, and to develop product candidates that act at these new potential drug targets;*

*our estimates regarding our future net losses, revenues, research and development expenses and sales and marketing, and general and administrative expenses;*

*our expectation that none of our product candidates will be commercially available until 2013, if at all;*

*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 belief that an increase in market rates would not have a material negative impact on the realized value of our investment portfolio; and*

*our involvement in potential claims and legal proceedings, the expected course and costs of existing claims and legal proceedings, and the potential outcomes and effects of both existing and potential claims and legal proceedings on our business, prospects, financial condition and results of operations.*

*Our 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 1A 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, 2010. 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 management's 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 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 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 ongoing clinical 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 product candidates and programs, we have retained all manufacturing, marketing and distribution rights.

**Table of Contents**

OMS103HP, one of our co-lead PharmacoSurgery product candidates, 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. This clinical program is planned to consist of separate trials conducted in North America and Europe. We expect data from the North American trial in mid-year 2012. We are in 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. We believe that OMS103HP will, if approved, be the first commercially available drug delivered directly to the surgical site to improve function following arthroscopic surgery. 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.

OMS302, our other co-lead PharmacoSurgery product candidate, is being evaluated in a Phase 3 clinical program for its safety and ability to maintain intraoperative pupil dilation (mydriasis) and reduce postoperative pain in patients undergoing intra-ocular lens replacement surgery. This clinical program is planned to consist of two trials that will enroll both cataract surgery and refractive lens exchange patients. We expect data from the initial Phase 3 trial in the first quarter of 2012. We plan to initiate the second trial following discussions with European regulatory authorities to ensure that data collected meet European expectations for marketing approval.

Our third PharmacoSurgery product candidate, 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 safe and well tolerated by the patients in this trial.

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 PPAR $\gamma$  program, we are developing proprietary compositions that include PPAR $\gamma$  agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine and alcohol. In our Plasmin program, we are advancing novel antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma. 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 caused by complement-activated inflammation and, in our PDE10 program, we are developing proprietary compounds to treat schizophrenia and other psychoses.

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 product candidates 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 14 orphan GPCRs. During the fourth quarter of 2010, we entered into an agreement with Vulcan Inc. and its affiliate, which we refer to collectively as 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 State of Washington's Life Sciences Discovery Fund Authority, or LSDF, under which we received a \$5.0 million grant award that will be paid against expenses that we incur or to reimburse us for the cost of assets that we purchase for 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 five-year warrants to purchase our common stock, each for 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 Limited, or 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.

We have incurred significant losses since our inception. As of September 30, 2011, our accumulated deficit was \$165.9 million and total shareholders' equity was \$4.1 million. We recognized net losses of \$6.5 million and \$7.6 million for the three months ended September 30, 2011 and 2010, respectively, and \$18.3 million and \$22.0 million for the nine

**Table of Contents**

months ended September 30, 2011 and 2010, 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 product candidates.

*Revenue*

We have recognized \$10.3 million of revenue from inception (June 16, 1994) through September 30, 2011, consisting 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 product candidates until we receive regulatory approval and commercialize the product candidates or until we potentially enter into collaborative agreements with third parties for the development and commercialization of our product candidates. As discussed below, we do not expect any of our current product candidates to be commercially available before 2013, if at all. We continue to pursue government and private grant funding as well as collaboration funding for our product candidates 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, contract research organizations, or CROs, clinical trial sites and collaborators or licensors;

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

third-party supplier expenses, which include costs for laboratory and other supplies.

Research and development expenses from inception (July 16, 1994) to September 30, 2011 were \$117.5 million. The following table illustrates our expenses associated with these activities for the three and nine months ended September 30, 2011:

	Three Months		Nine Months Ended	
	Ended September 30, 2011	2010	September 30, 2011	2010
	(in thousands)			
<b>Direct external expenses:</b>				
Clinical research and development:				
OMS103HP	\$ 506	\$ 1,636	\$ 2,454	\$ 4,585
OMS302	773	445	1,375	671
Other clinical programs	255	86	445	125
Total clinical research and development	1,534	2,167	4,274	5,381
Preclinical research and development	1,320	435	2,602	3,443



Edgar Filing: OMEROS CORP - Form 10-Q

<b>Total direct external expenses</b>	2,854	2,602	6,876	8,824
Internal, overhead and other expenses	2,282	2,448	7,304	7,050
Stock-based compensation expense	185	266	643	644
<b>Total research and development expenses</b>	<b>\$ 5,321</b>	<b>\$ 5,316</b>	<b>\$ 14,823</b>	<b>\$ 16,518</b>

## **Table of Contents**

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 research activities, preclinical studies and laboratory supplies. 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 product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. While we are currently focused on advancing each of our product development programs, our future research and development expenses will depend on the clinical success of each product candidate, as well as ongoing assessments of each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates 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 product candidates 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 product candidates to be commercially available before 2013, 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 Income (Expense)*

Other income (expense) consists primarily of rental income received under subleases for use of a portion of our vivarium and laboratory facility.

## **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 accounting principles generally accepted in the United

## **Table of Contents**

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

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 since inception relates to 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

## **Table of Contents**

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.

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.

## **Results of Operations**

### *Comparison of Three Months Ended September 30, 2011 and September 30, 2010*

*Revenue.* Revenue was \$987,000 for the three months ended September 30, 2011, compared to \$254,000 for the three months ended September 30, 2010. This increase was primarily due to our recognition of \$936,000 of revenue in connection with the Vulcan and LSDF agreements for our GPCR program, partially offset by the completion of preclinical research funded by grants from the National Institutes of Health, or NIH.

*Research and Development Expenses.* Research and development expenses were \$5.3 million for each of the two quarters ended September 30, 2011 and September 30, 2010. Compared to the third quarter of 2011, the third quarter of 2010 had lower preclinical program expenses but higher clinical trial costs in connection with our arthroscopic and ophthalmology programs.

*General and Administrative Expenses.* General and administrative expenses were \$1.8 million for the three months ended September 30, 2011 compared to \$2.4 million for the three months ended September 30, 2010. General and administrative expenses for both periods consist principally of personnel, overhead, stock-based compensation, patent costs, and professional fees for legal, consulting and audit services. This relative decrease in general and administrative expenses in the 2011 quarter is primarily attributable to lower legal costs and one-time expenses incurred in connection with establishing an equity financing facility with Azimuth in the 2010 quarter.

*Interest Expense.* Interest expense was \$528,000 for the three months ended September 30, 2011 compared to \$362,000 for the three months ended September 30, 2010. This increase was primarily attributable to an increase in the principal on our notes payable balance resulting from our borrowing an additional \$10.0 million from Oxford Finance Corporation, or Oxford, in March 2011.

*Other Income.* Other income was \$171,000 for the three months ended September 30, 2011 compared to \$189,000 for the three months ended September 30, 2010. Other income consists primarily of rental income received under subleases for use of a portion of our vivarium and laboratory facilities.

### *Comparison of Nine Months Ended September 30, 2011 and September 30, 2010*

*Revenue.* Revenue was \$3.4 million for the nine months ended September 30, 2011 compared to \$1.1 million for the nine months ended September 30, 2010. This increase was primarily due to our recognition of revenue of \$2.9 million in connection with the Vulcan and LSDF agreements for our GPCR program, offset by the completion of preclinical research funded by NIH grants.

## **Table of Contents**

*Research and Development Expenses.* Research and development expenses were \$14.8 million for the nine months ended September 30, 2011 compared to \$16.5 million for the nine months ended September 30, 2010. This decrease in 2011 was primarily due to lower clinical trial expenses in 2011 and one-time licensing fees in 2010.

*General and Administrative Expenses.* General and administrative expenses were \$6.1 million for the nine months ended September 30, 2011 compared to \$6.2 million for the nine months ended September 30, 2010. General and administrative expenses for both periods consist principally of personnel, overhead, stock-based compensation and patent costs as well as professional fees for legal, consulting and audit services.

*Interest Expense.* Interest expense was \$1.3 million for the nine months ended September 30, 2011 compared to \$1.2 million for the nine months ended September 30, 2010. This increase was primarily due to a higher average principal balance on our outstanding notes payable in 2011 resulting from our borrowing of \$10.0 million from Oxford in March 2011, partially offset by a lower interest rate.

*Other Income.* Other income was \$526,000 for the nine months ended September 30, 2011 compared to \$606,000 for the nine months ended September 30, 2010. Other income consists primarily of rental income received under subleases for use of a portion of our vivarium and laboratory facilities.

## **Liquidity and Capital Resources**

From inception to September 30, 2011, we have financed our operations primarily through private and public placements of equity securities for proceeds totaling \$139.2 million; 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 our GPCR program funding agreement with Vulcan pursuant to which we received \$20.0 million. As of September 30, 2011, we had \$32.9 million in cash, cash equivalents and short-term investments. Our cash, cash equivalents and short-term investment balances are held principally in interest-bearing instruments, including money-market accounts. Cash in excess of immediate requirements is invested in accordance with established guidelines to preserve principal and maintain liquidity.

### *Comparison of Nine Months Ended September 30, 2011 and September 30, 2010*

*Operating Activities.* Net cash used in operating activities was \$18.3 million for the nine months ended September 30, 2011 compared to \$21.1 million for the nine months ended September 30, 2010. 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 decrease in net cash used in operating activities was primarily due to decreased development expenses, including lower costs to support our clinical activities during the 2011 period and one-time licensing fees incurred during the 2010 period associated with our MASP-2 and GPCR programs. Also, the 2011 period includes the recognition of revenue that was deferred in connection with the Vulcan funding agreement.

*Investing Activities.* Net cash provided by investing activities was \$9.6 million for the nine months ended September 30, 2011 compared to net cash provided by investing activities of \$27.0 million for the nine months ended September 30, 2010. Since our inception, investing activities, other than purchases and maturities of short-term and long-term investments, consist primarily of purchases of property and equipment. In 2010, investing activities also included our acquisition of intellectual property assets from Patobios and our subsequent reimbursement of the purchase price by Vulcan. Cash flows from investing activities primarily reflect large amounts of cash used to purchase short-term investments and receipts from the sale and maturity 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 an understanding of our liquidity and capital resources.

---

## **Table of Contents**

*Financing Activities.* Net cash provided by financing activities was \$10.4 million for the nine months ended September 30, 2011, primarily as a result of proceeds from the borrowing of an additional \$10.0 million from Oxford in March 2011. Net cash used in financing activities was \$3.9 million for the nine months ended September 30, 2010, primarily as a result of principal payments due under our notes payable to BlueCrest Venture Finance Master Fund Limit, or BlueCrest, which we subsequently repaid in full.

### *GPCR Program Funding Agreements*

In October 2010, we entered into an agreement with Vulcan pursuant to which we received \$20.0 million for our GPCR program. Also in October 2010, we entered into an agreement with LSDF under which we received a \$5.0 million grant award that will be paid as reimbursement of expenses that we incur and equipment purchases we make for our GPCR program. Following the execution of the funding agreement with Vulcan, in November 2010 we purchased from Patobios intellectual property assets related to a proprietary cellular redistribution assay for approximately \$10.8 million, which consisted of approximately \$7.6 million paid in cash and 379,039 shares of our common stock with a fair value of approximately \$3.2 million.

### *Oxford Loan Agreement*

In October 2010, we entered into a \$20.0 million loan and security agreement with 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, using approximately \$9.0 million of the proceeds to repay all outstanding amounts due under our loan and security agreement with BlueCrest as well as a 1.0% prepayment fee on the then-outstanding principal. In March 2011, we borrowed the second tranche of \$10.0 million, or Tranche 2, from Oxford. As of September 30, 2011, our notes payable balance was \$20.4 million, consisting primarily of notes payable to Oxford. We cannot borrow any additional amounts from Oxford under our agreement.

Interest on the notes we issued to Oxford for Tranche 1 and Tranche 2 accrues at annual fixed rates of 8.55% and 8.56%, respectively. Payments due under both Tranche 1 and Tranche 2 are interest only, payable monthly, in arrears, through October 31, 2011. Beginning November 1, 2011, 36 payments of principal and interest are payable monthly, in arrears, which will result in an increase in our monthly payments. All unpaid principal and accrued and unpaid interest under both tranches are due and payable on the maturity date of the notes, October 21, 2014.

We made facility fee payments to Oxford of \$50,000 for each of Tranche 1 and Tranche 2. 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). As security for our obligations under the loan agreement, we granted Oxford a security interest in substantially all of our assets, excluding intellectual property. We may prepay all, but not less than all, of the outstanding principal and accrued and unpaid interest of either Tranche 1 or Tranche 2 at any time upon prior notice to Oxford and the payment of a fee equal to 1.0% of the then-outstanding principal amount of the tranche being prepaid. In connection with entering into the Oxford loan agreement, we incurred debt issuance costs of \$227,000.

The Oxford loan agreement contains customary affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, and repurchase stock, in each case subject to customary exceptions for a credit facility of this size and type. The loan agreement contains no cash covenant. The loan agreement also contains customary events of default that include, among other things, non-payment defaults, inaccuracy of representations and warranties, covenant defaults, material adverse change default (as defined in the agreement), cross default to material indebtedness, bankruptcy and insolvency defaults, material judgment defaults, and a change of control default. We believe that we comply with the material adverse change clause, and no scheduled loan payments have been accelerated as a result of this provision. The occurrence of an event of default could result in the acceleration of the obligations under the loan agreement. Under certain circumstances, a default interest rate will apply on all obligations during the existence of an event of default at a per annum rate equal to 5.0% above the otherwise applicable interest rate.

**Table of Contents***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. From time to time over the 24-month term, and in our sole discretion, we may present Azimuth with draw down notices requiring Azimuth to purchase a specified dollar amount of shares of our common stock, based on the volume-weighted average price per share on each of 10 consecutive trading days, or the draw down period, with the total dollar amount of each draw down subject to certain agreed-upon limitations based on the market price of our common stock at the time of the draw down. The purchase price for these shares equals the daily volume-weighted average price of our common stock on each date during the draw down period on which shares are purchased, less a discount ranging from 3.00% to 6.00%, based on a minimum price that we specify. In addition, in our sole discretion, but subject to certain limitations, we may require Azimuth to purchase a percentage of the daily trading volume of our common stock for each trading day during the draw down period. 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 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 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 The Stanley Medical Research Institute, or SMRI, to develop a proprietary product candidate 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 September 30, 2011, 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. As of September 30, 2011, all grant amounts pertaining to this agreement previously recorded as deferred revenue in the accompanying balance sheet have been recognized as revenue.

*Funding Requirements*

We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months. We base this estimate on assumptions that may prove to be wrong and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, 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;

**Table of Contents**

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 product candidates;

the terms and timing of payments of any collaborative or licensing agreements that we have or may establish, including pursuant to our agreements with Daiichi-Sankyo Company, Helion, LSDF and Vulcan;

market acceptance of our approved products, should they gain approval;

the cost, timing and outcomes of the regulatory processes for our product candidates;

the costs of commercialization activities, including product manufacturing, marketing, sales and distribution;

the number and characteristics of product candidates that we pursue;

the cost of establishing clinical and commercial supplies of our product candidates;

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 OMS103HP, OMS302 and other product candidates; and

the extent to which we draw down funds under our committed equity line financing facility with Azimuth.

We do not anticipate generating revenue from the sale of our product candidates until 2013 at the earliest. 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. 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. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently, or enter into corporate collaborations at an earlier stage of development than we might otherwise choose. In addition, any future equity funding will dilute the ownership of our equity investors.





---

## **Table of Contents**

### **Contractual Obligations and Commitments**

There have been no significant changes during the nine months ended September 30, 2011 to the items that we disclosed as our contractual obligations and commitments in our Form 10-K for the year ended December 31, 2010, except as follows:

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, pursuant to which we received an exclusive license to PDE7 inhibitors claimed in certain patents and pending patent applications owned by Daiichi for use in the treatment of movement disorders and other specified indications. On January 5, 2011 we entered into an amendment to the agreement to include addiction and compulsive disorders in the field of use. Pursuant to the amended agreement, the development and sales milestones have also been expanded to cover two separate indications for the licensed PDE7 inhibitors, with movement disorders and other specified indications within the original field defined as one indication and addiction and compulsive disorders defined as the second indication. Additionally, the aggregate total of milestone payments potentially payable to Daiichi has increased to \$30.2 million for the two indications from \$23.5 million for only one indication. If only one of the two indications is advanced through the milestones, the total milestone payments would remain at \$23.5 million. These development and sales milestone payments are payable upon the achievement of certain events related to each of the two separate indications, 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. No other material terms of the agreement were amended.

On March 25, 2011, we borrowed Tranche 2 from Oxford, which bears interest at an annual fixed rate of 8.56%. Payments due under Tranche 2 are interest only, payable monthly, in arrears, through October 31, 2011. Beginning November 1, 2011, 36 payments of principal and interest are payable monthly, in arrears. All unpaid principal and accrued and unpaid interest on Tranche 2 are due and payable on October 21, 2014. We made a facility fee payment to Oxford of \$50,000 for Tranche 2. Upon the last payment date of the amounts borrowed under Tranche 2, whether on the maturity date, on the date of any prepayment or on the date of acceleration in the event of a default, we will be required to pay Oxford a final payment fee equal to 4.0% of Tranche 2 (\$400,000).

On March 25, 2011, we also entered into an amendment to our loan and security agreement with Oxford to amend the prepayment provisions of the agreement. Prior to the amendment, if we elected to prepay any outstanding amounts, the prepayment clause required us to prepay all of the amounts outstanding under Tranche 1 and Tranche 2, and we were also required to pay a prepayment fee equal to 1.0% of the then-outstanding principal amounts of Tranche 1 and Tranche 2. As a result of the amendment, we are now permitted to prepay all of the outstanding principal and accrued and unpaid interest of either Tranche 1 or Tranche 2 at any time upon prior notice to Oxford and the payment of a fee equal to 1.0% of the then-outstanding principal amount of the tranche being prepaid.

### **Off-Balance Sheet Arrangements**

Since our inception, 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 a variety of securities of high credit quality. As of September 30, 2011, we had cash, cash equivalents and short-term investments of \$32.9 million. We have invested these funds in highly liquid, investment-grade securities in accordance with our investment policy. The 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.

---

**Table of Contents**

**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 September 30, 2011. 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 September 30, 2011, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

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

**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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 National Institutes of Health, or 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. We subsequently voluntarily reported to the NIH Mr. Klein's whistleblower report and the audit committee findings; the NIH confirmed to us in writing that it was satisfied with our handling of the grant matters that were the subject of Mr. Klein's whistleblower report.

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. Mr. Klein alleges in his complaint that we, among other things, violated the Federal False Claims Act, wrongfully discharged his employment in violation of public policy and defamed him. Mr. Klein seeks, among other things, damages in an amount to be proven at trial, actual litigation expenses and his reasonable attorneys' fees and damages for loss of future earnings. 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 a qui tam claim asserted on behalf of the U.S. government under the Federal False Claims Act. The qui tam claim is 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 fees and costs. On October 17, 2011, the U.S. government filed a notice of its election to decline intervention in the qui tam claim. This election not to intervene in Mr. Klein's qui tam claim does not prevent Mr. Klein from continuing this claim, nor does it affect his other claims against Omeros or our claims against Mr. Klein. 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 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.

---

**Table of Contents**

**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.*

**Risks Related to Our Product Candidates, Programs and Operations**

**Our success may largely depend on the success of at least one of our co-lead PharmacoSurgery product candidates, OMS103HP and OMS302, and we cannot be certain that either of them will receive regulatory approval or be successfully commercialized. If we are unable to commercialize OMS103HP or OMS302, 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 product candidates OMS103HP for use during arthroscopic partial meniscectomy surgery and OMS302 for use during cataract and other lens replacement surgery. We have not yet obtained regulatory approval to market either of these product candidates 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 product candidates successfully.

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

We are now conducting a Phase 3 clinical program evaluating OMS103HP in patients undergoing partial meniscectomy surgery. This clinical program is planned to consist of two trials conducted in North America and Europe. We expect data from the North American trial in mid-year 2012. We are in 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. Similar to the ACL reconstruction indication, OMS103HP demonstrated a drug effect in an earlier Phase 2 clinical trial in patients undergoing partial meniscectomy. Although the Phase 2 meniscectomy data show a drug effect, 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 their prespecified efficacy endpoints. 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 addition, we have initiated a Phase 3 clinical program to evaluate OMS302 in patients undergoing cataract surgery and refractive lens exchange. This clinical program is planned to consist of two trials that will enroll both cataract surgery and refractive lens exchange patients. We expect data from the initial Phase 3 trial in the first quarter of 2012. We plan to initiate the second Phase 3 trial following discussions with European regulatory authorities to determine whether data collected meet European expectations for marketing approval. We can provide no assurance that the data from this clinical program will demonstrate a drug effect or that the trials will meet their prespecified efficacy endpoints. Further, if we are delayed or unable to commence and complete the second clinical trial of OMS302, we may be significantly delayed in seeking, or be unable to seek, marketing approval of the product candidate.

We expect to incur significant clinical development and commercialization costs related to OMS103HP and OMS302, and if the resulting data for one or both of these product candidates 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

---

**Table of Contents**

of our stock could decline significantly. Even if the data are positive for either of our lead product candidates, the FDA and other regulatory authorities may decide that our clinical trials or data are insufficient for approval of the product candidate and require additional preclinical, clinical or other studies. If these product candidates do not subsequently receive regulatory approval or if approval is delayed beyond our expectations, or if neither product is successfully commercialized, we may not be able to generate revenue, become profitable, fund the development of our other product candidates or preclinical development programs or continue our operations.

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

Both before and after approval of our product candidates, we, our product candidates, 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; fines and other monetary penalties; unanticipated expenditures; delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating restrictions; injunctions; and criminal prosecution. We or the U.S. Food and Drug Administration, or FDA, or an institutional review board, or IRB, 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.

Our product candidates 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 product candidates for sale in the United States. All of our product candidates 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 product candidates and require additional preclinical, clinical or other studies. As we develop our product candidates, 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 product candidates 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 product candidates 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 product candidates, or may never be able to obtain marketing approval.

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

---

## **Table of Contents**

**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 the product candidate, can provide no assurances that it will demonstrate efficacy.**

In addition to OMS103HP and OMS302, our success could also depend on the successful commercialization of our third PharmacoSurgery product candidate, 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 and can provide no assurances that 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 product candidates or our preclinical programs or continue our operations.

**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 \$18.3 million and \$22.0 million for the nine months ended September 30, 2011 and 2010, respectively. As of September 30, 2011, we had an accumulated deficit of approximately \$165.9 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 product candidates until 2013 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 product candidates, to develop a market for our potential products, to successfully transition from a company with a research and development focus to a company capable of commercializing our product candidates and to attract and retain qualified management as well as technical and scientific staff.

**If our clinical trials are delayed, we may be unable to develop our product candidates 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, IRBs 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 IRBs or other governing 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 or unacceptable design;

## Edgar Filing: OMEROS CORP - Form 10-Q

an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;

the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval;

an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation;

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

the placement of a clinical hold on a trial.

## Table of Contents

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 IRBs 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 approval process, would delay our receipt of product revenue and could make it difficult to raise additional capital. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. 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.

**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 OMS103HP, OMS302 or our other product candidates, 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 OMS103HP for use in arthroscopic partial meniscectomy surgery;

complete the Phase 3 clinical program of OMS302 for use in cataract surgery and refractive lens exchange;

purchase the equipment and research tools and pay all of the related research and development costs necessary to screen orphan GPCRs and commence related medicinal chemistry efforts as required pursuant to our GPCR program funding agreements with Vulcan and LSDF;

scale-up and produce clinical supplies of product candidates, including for our Plasmin, PDE10, PDE7 and MASP-2 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 milestone payments to our collaborators;

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

initiate and conduct clinical trials for other product candidates; and

launch and commercialize any product candidates 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 OMS103HP and OMS302, which would prevent us from seeking marketing approval and generating sales revenue for one or both of those product candidates. 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

## **Table of Contents**

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 OMS103HP or OMS302 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. 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 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 existing and future product candidates, including our co-lead product candidates OMS103HP and OMS302, 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 product candidates, including OMS103HP and OMS302, the commercial success of these product candidates will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community. If our product candidates 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 candidate 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 surgical procedure or condition for which the product is approved;

acceptance by physicians of each product as a safe and effective treatment;

perceived advantages over alternative treatments;

relative convenience and ease of administration;

the availability of adequate reimbursement by third parties;

the prevalence and severity of adverse side effects;

publicity concerning our products or competing products and treatments; and

our ability to obtain sufficient third-party reimbursement for our products.

---

## **Table of Contents**

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 product candidates 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 product candidates, our growth will be significantly harmed.

**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, we may not be able to obtain regulatory approval for or commercialize our product candidates.**

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 is conducted in accordance with applicable regulations, and that our clinical trials are conducted in accordance with applicable regulations, the relevant protocol and within the context of approvals by an IRB. 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 product candidates.

**If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, 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 product candidates that we develop ourselves. Factors that may inhibit our efforts to commercialize our approved product candidates 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 our approved product candidates;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

We do not intend to manufacture our product candidates 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 product candidates, 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

product candidates could materially harm our business and prospects.

---

**Table of Contents**

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

Contract manufacturers that we select to manufacture our product candidates 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 product candidates. Once a product candidate 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, or cGMP, 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 cGMP requirements or with other FDA, state, local and foreign regulatory requirements. We have little control over our contract manufacturers' compliance with these regulations and standards or with their quality control and quality assurance procedures but we are responsible for their compliance. For the liquid formulation of OMS103HP and our other product candidates, large-scale manufacturing processes that have been developed 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 issuance of untitled letters and/or warning letters from authorities, as well as sanctions being imposed on us, including fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product candidate 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 product candidates, 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 product candidates 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 would 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 product candidates.

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

We must purchase from third-party suppliers the ingredients necessary for our contract manufacturers to produce our PharmacoSurgery product candidates 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 product candidates, 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

---

**Table of Contents**

we are unable to obtain and then supply these ingredients to our contract manufacturer for our clinical trials, potential regulatory approval of our product candidates would be delayed, significantly impacting our ability to develop our product candidates, which would materially affect our ability to generate revenue from the sale of our product candidates.

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

Should we decide to use active ingredients in any of our product candidates 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 preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these product candidates. 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 product candidates from these programs.

**Our agreements with Vulcan and LSDF contain covenants that may limit our ability to redirect research and development efforts away from our GPCR program to other programs that may be more profitable or for which there is a greater likelihood of success.**

In October 2010, we received \$20.0 million from Vulcan for our GPCR program, as well as an additional \$5.0 million grant award from LSDF that will be paid against expenses that we incur for our GPCR program. In exchange for these payments, we agreed to pay Vulcan and LSDF a portion of net proceeds that we receive from the GPCR program. Pursuant to our agreements with Vulcan and the LSDF, we are required to comply with certain covenants, including ones that require us (1) to use commercially reasonable efforts to screen at least 75% of the currently known human Class A orphan GPCRs within 19 months from the date of the agreements, subject to possible extensions, and (2) to commence a medicinal chemistry effort focused on developing a product candidate with respect to one orphan GPCRs and cause at least six employees and consultants to dedicate a substantial portion of their time to such activities. These covenants require us to commit substantial resources to activities that we may, absent such covenants, otherwise elect to abandon or delay in favor of other opportunities or to preserve our cash. Further, we cannot guarantee that we will be able to comply with these covenants and, if we do not, Vulcan or LSDF could declare that we are in default, which could significantly harm our business and prospects and could cause our stock price to decline.

**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 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 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.

---

**Table of Contents**

**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 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.

**LSDF may not fund all of the \$5.0 million grant award.**

LSDF's \$5.0 million grant award is only paid against certain costs we incur in the GPCR program. As of September 30, 2011, we had received \$3.3 million of funding against reimbursable expenses pursuant to the grant award. If LSDF believes that we have breached our agreement before we have received the entire \$5.0 million available under the grant award, LSDF may refuse to provide us any further funding, in which case we will have fewer resources to advance our GPCR program and to meet the covenants related to our GPCR program set forth in our agreements with Vulcan and LSDF.

**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.

**Our ability to pursue the development and commercialization of product candidates 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, or MRC, and Helion. The continued maintenance of these agreements requires us to undertake development activities and, if regulatory approval for marketing is obtained, to pay royalties to each of these organizations upon commercialization of a MASP-2 product candidate. In addition, we are obligated to pay Helion up to \$6.9 million upon the achievement of certain events related to a MASP-2 product candidate, 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 product candidates from our MASP-2 program depends on our maintaining these exclusive licenses, which cannot be assured.



## **Table of Contents**

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

Any product candidate from our Plasmin or MASP-2 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 Plasmin or MASP-2 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 product candidates for one of these programs, clinical trials or the development of any such product candidate 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 programs may not produce product candidates that are suitable for clinical trials or that can be successfully commercialized or generate revenue through partnerships.**

Any product candidates from our preclinical programs, including our GPCR, Plasmin, PDE7, MASP-2 and PDE10 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 product candidates 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 product candidates that are suitable for clinical testing. For example, we have not yet generated any product candidates 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 product candidates that successfully complete preclinical or clinical testing. If we are unable to develop product candidates, potential corporate partners may be unwilling to enter into partnership agreements with us. We also cannot be certain that any product candidates 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 product candidates, we may expend our limited resources to pursue a particular candidate or candidates and fail to capitalize on candidates 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 product candidates that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential and may not be able to progress development programs, including our GPCR program, as rapidly as otherwise possible. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Further, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate 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.

---

## **Table of Contents**

### **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 product candidates, 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 product candidates 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 have terms that will expire December 12, 2014 (for OMS103HP, OMS302 (in Europe) and OMS201) and September 24, 2022 (for OMS103HP). If our pending PharmacoSurgery patent applications issue as patents, the expiration dates of those patents will be July 30, 2023 for OMS302 and March 17, 2026 for OMS201, not taking into account any extensions due to potential adjustment of patent terms resulting from USPTO delays. 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 product candidates and materially harm our business.

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

we might not have been the first to make the inventions covered by any of our patents, if issued, or our pending patent applications;

we might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or products or duplicate any of our technologies or products;

we may not be able to generate sufficient data to fully support patent applications that protect the entire breadth of developments expected to result from our development programs, including the GPCR program;

---

**Table of Contents**

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

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

---

## **Table of Contents**

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 the technology. 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 another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference 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.

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

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

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

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies other than on the life of Gregory Demopulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, could delay 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

---

**Table of Contents**

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 may consume our time and resources, 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 it was retaliatory. We subsequently voluntarily reported to the NIH Mr. Klein's whistleblower report and the audit committee findings; the NIH confirmed to us in writing that it was satisfied with our handling of the grant matters that were the subject of Mr. Klein's whistleblower report.

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, 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, damages in an amount to be proven at trial, actual litigation expenses and his reasonable attorneys' fees and damages for loss of future earnings. 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 a qui tam claim asserted on behalf of the U.S. government under the Federal False Claims Act. The qui tam claim is 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 fees and costs. On October 17, 2011, the U.S. government filed a notice of its election to decline intervention in the qui tam claim, but the election not to intervene in Mr. Klein's qui tam claim does not prevent Mr. Klein from continuing this claim or his other claims and does not affect our claims against Mr. Klein. Although we have been advised by outside counsel that we have meritorious defenses to Mr. Klein's allegations, and we are defending against the claims vigorously, 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 may consume our time and resources, 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.

**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 and the Dodd-Frank Wall Street Reform and 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 such as "say-on-pay" voting by shareholders. 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.

## **Table of Contents**

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

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

### **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 product candidates, that reach the market before our product candidates, or that otherwise negatively affect the market, we may not achieve commercial success. For example, we are developing PDE10 inhibitors to identify a product candidate for use in the treatment of schizophrenia and other psychotic disorders. Other pharmaceutical companies, many with significantly greater resources than we have, are also developing PDE10 inhibitors for the treatment of schizophrenia and other psychotic disorders and these companies may be further along in development. The failure of a PDE10 inhibitor product candidate from any of our competitors to demonstrate safety or efficacy in clinical trials may negatively reflect on the ability of our PDE10 inhibitor product candidates 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 developed from our product candidates 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 developed from our product candidates;

commercialize competing products before we can launch any products developed from our product candidates;

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.

---

## **Table of Contents**

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

**Our product candidates 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 product candidates if and when any of them are approved.**

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

restrictions on such product candidates or manufacturing processes;

withdrawal of the product candidates 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 product candidates 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 product candidates 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.

---

## **Table of Contents**

**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 product candidates 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 product candidates to market, these products may not be considered cost-effective, and the amount reimbursed for any product candidates may be insufficient to allow us to sell our product candidates 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 product candidates 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 product candidates or to surgeons for the administration and delivery of these product candidates will be considered adequate to justify the use of these product candidates. There may be significant delays in obtaining reimbursement coverage for newly approved product candidates 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 candidate 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 candidate 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 product candidates 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 candidate. If the reimbursement we are able to obtain for any product candidate 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 candidate's safety and efficacy and could limit our ability to sell one or more product candidates, if approved, by preventing or interfering with commercialization of our product candidates. 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 product candidates progresses, or that future claims against us will be covered by our product liability insurance. Although we currently have product liability insurance coverage for our clinical trials, our insurance coverage may not reimburse us or may be insufficient to reimburse us for any or all expenses or losses we may suffer. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage could have a material adverse effect on our business, financial condition and results of operations.



**Table of Contents**

**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.**

We completed the initial public offering of shares of our common stock in October 2009 at a price of \$10.00 per share. Subsequently, our common stock has traded as low as \$3.16 per share through November 3, 2011. 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 include:

results from our clinical development programs;

FDA or international regulatory actions, including failure to receive regulatory approval for any of our product candidates;

announcements regarding the progress of our GPCR program;

failure of any of our product candidates, 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 product candidates 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 we had a notes-payable balance of \$20.0 million as of September 30, 2011;

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

changes in earnings estimates or recommendations by securities analysts;

any major change in our board or management;

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

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

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

---

## **Table of Contents**

**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 product candidates 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 product candidates 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 product candidates 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.

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

Approximately 5.9 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

**Table of Contents**

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. 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**

<b>Exhibit</b>	
<b>Number</b>	<b>Description</b>
12.1	Ratio of Earnings to Fixed Charges
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\* 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.

**Table of Contents**

**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**

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

President, Chief Executive Officer

and Chairman of the Board of Directors

Date: November 8, 2011