

OMEROS CORP  
Form 10-Q  
August 10, 2010

**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**

**For the quarterly period ended June 30, 2010**

**or**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number: 001-34475**

**OMEROS CORPORATION**

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

**Washington**  
**(State or other jurisdiction of**  
**incorporation or organization)**

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

**1420 Fifth Avenue, Suite 2600**  
**Seattle, Washington**  
**(Address of principal executive offices)**

**98101**  
**(Zip Code)**

**(206) 676-5000**

**(Registrant's telephone number, including area code)**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ 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 ☒

Smaller reporting  
company ☐

(Do not check if a 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 August 6, 2010, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 21,487,480.



**OMEROS CORPORATION**  
**FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2010**  
**INDEX**

	<b>Page</b>
<b><u>Part I Financial Information</u></b>	
<u>Item 1. Financial Statements</u>	3
<u>Consolidated Balance Sheets as of June 30, 2010 and December 31, 2009</u>	3
<u>Consolidated Statements of Operations for the Six Months Ended June 30, 2010 and 2009 and for the period from June 16, 1994 (inception) through June 30, 2010</u>	4
<u>Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2010 and 2009 and for the period from June 16, 1994 (inception) through June 30, 2010</u>	5
<u>Notes to the Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	24
<u>Item 4. Controls and Procedures</u>	25
<b><u>Part II Other Information</u></b>	
<u>Item 1. Legal Proceedings</u>	25
<u>Item 1A. Risk Factors</u>	25
<u>Item 6. Exhibits</u>	45
<u>Signatures</u>	46
<u>EX-10.2</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-32.2</u>	

**Table of Contents****PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**CONSOLIDATED BALANCE SHEETS**  
**(In thousands)**

	<b>June 30, 2010 (unaudited)</b>	<b>December 31, 2009</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,873	\$ 820
Short-term investments	39,010	59,485
Grant and other receivables	935	248
Prepaid expenses and other current assets	214	111
Total current assets	43,032	60,664
Property and equipment, net	1,498	1,086
Restricted cash	193	193
Other assets	63	119
Total assets	\$ 44,786	\$ 62,062
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,100	\$ 2,620
Accrued expenses	3,267	2,837
Deferred revenue	478	702
Current portion of notes payable	5,269	4,931
Total current liabilities	10,114	11,090
Notes payable, less current portion	4,874	7,827
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 June 30, 2010 (unaudited) and December 31, 2009;		
Issued and outstanding shares 21,434,491 and 21,285,577 at June 30, 2010 (unaudited) and December 31, 2009, respectively	214	213
Additional paid-in capital	162,385	161,227
Accumulated other comprehensive income		41
Deficit accumulated during the development stage	(132,801)	(118,336)
Total shareholders' equity	29,798	43,145

Total liabilities and shareholders' equity	\$	44,786	\$	62,062
--	----	--------	----	--------

See notes to consolidated financial statements

3

---

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>Six Months Ended</b>		<b>Period</b>
	<b>June 30,</b>		<b>June 30,</b>		<b>from</b>
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>	<b>June 16,</b>
					<b>1994</b>
					<b>(Inception)</b>
					<b>through</b>
					<b>June 30,</b>
					<b>2010</b>
Grant revenue	\$ 497	\$ 371	\$ 875	\$ 568	\$ 5,712
Operating expenses:					
Research and development	6,120	4,577	11,202	8,599	90,365
Acquired in-process research and development					10,891
General and administrative	2,011	1,475	3,732	2,885	41,488
Total operating expenses	8,131	6,052	14,934	11,484	142,744
Loss from operations	(7,634)	(5,681)	(14,059)	(10,916)	(137,032)
Investment income	21	61	38	142	5,415
Interest expense	(409)	(575)	(861)	(1,165)	(3,692)
Other income, net	218	86	417	348	2,508
Net loss	\$ (7,804)	\$ (6,109)	\$ (14,465)	\$ (11,591)	\$ (132,801)
Basic and diluted net loss per common share	\$ (0.36)	\$ (2.09)	\$ (0.68)	\$ (3.96)	
Weighted-average shares used to compute basic and diluted net loss per common share	21,381,216	2,929,690	21,337,556	2,929,397	

See notes to consolidated financial statements

Table of Contents

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

	<b>Six Months Ended June 30,</b>		<b>Period from June 16, 1994 (Inception) through June 30, 2010</b>
	<b>2010</b>	<b>2009</b>	
<b>Operating activities</b>			
Net loss	\$ (14,465)	\$ (11,591)	\$ (132,801)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	261	245	2,263
Stock-based compensation expense	1,000	939	12,652
Change in fair value of preferred stock warrant values and success fee liability		55	(253)
Non-cash interest expense	82	125	390
Realized loss on sale of investment securities	33	8	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	(687)	(363)	365
Prepaid expenses and other current and noncurrent assets	(68)	80	(198)
Deferred public offering costs		(557)	(1,948)
Accounts payable and accrued expenses	(1,158)	30	3,707
Deferred revenue	(224)	1,037	(822)
Net cash used in operating activities	(15,226)	(9,992)	(103,531)
<b>Investing activities</b>			
Purchases of property and equipment	(605)	(51)	(2,677)
Purchases of investments	(5)	(3,200)	(148,109)
Proceeds from the sale of investments	20,117	950	63,833
Proceeds from the maturities of investments	323	573	45,026
Cash paid for acquisition of nura, net of cash acquired of \$87			(212)
Net cash provided by (used in) investing activities	19,830	(1,728)	(42,139)
<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			16,928



Edgar Filing: OMEROS CORP - Form 10-Q

Payments on notes payable	(2,710)	(1,581)	(9,286)
Proceeds from issuance of common stock upon exercise of stock options	159	10	829
Proceeds from issuance of convertible preferred stock, net of issuance costs		1,851	78,234
Other, net		(3)	26
Net cash (used in) provided by financing activities	(2,551)	277	148,543
Net (decrease) increase in cash and cash equivalents	2,053	(11,443)	2,873
Cash and cash equivalents at beginning of period	820	12,726	
Cash and cash equivalents at end of period	\$ 2,873	\$ 1,283	\$ 2,873
<b>Supplemental cash flow information</b>			
Cash paid for interest	\$ 746	\$ 1,041	\$ 3,209
Preferred stock and common stock issued in connection with nura acquisition	\$	\$	\$ 14,070

See notes to consolidated financial statements

## **Table of Contents**

### **Note 1 Organization and Significant Accounting Policies**

#### *Organization*

We are a biopharmaceutical company committed to discovering, developing and commercializing products focused on inflammation 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. As substantially all of our efforts have been devoted to conducting research and development of our products, to developing our patent portfolio and to raising equity capital, we are considered to be in the development stage.

#### *Basis of Presentation*

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of June 30, 2010 and for the three and six months ended June 30, 2010 and 2009, includes all adjustments, which include only normal recurring adjustments, necessary to present fairly our interim financial information. The consolidated balance sheet at December 31, 2009 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 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, 2009.

Our consolidated financial statements include the financial position and results of operations of 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 us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

#### *Recent Accounting Pronouncements*

In October 2009, the Financial Accounting Standards Board, or FASB, issued new guidance for multiple-deliverable revenue arrangements. The new guidance addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence; (b) third-party evidence; or (c) estimates. This guidance also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling-price method. In addition, this guidance significantly expands required disclosures related to a vendor's multiple-deliverable revenue arrangements. We expect to adopt this guidance on January 1, 2011 and to apply it prospectively for revenue arrangements entered into or materially modified after the date of adoption.

In March 2010, the FASB issued new guidance for recognizing revenue under the milestone method. This new guidance allows an entity to make a policy election to recognize a substantive milestone in its entirety in the period in which the milestone is achieved. The new guidance also requires an entity that makes this policy election to disclose the following: (a) a description of the overall arrangement, (b) a description of each milestone and related contingent consideration, (c) a determination of whether each milestone is considered substantive, (d) the factors considered in determining whether the milestone is substantive and (e) the amount of consideration recognized during the period for

**Table of Contents**

milestones. We expect to adopt this guidance on January 1, 2011 and to apply it prospectively for revenue arrangements entered into or materially modified after the date of adoption

The impact of the above guidance will be dependent on the terms and structure of revenue generating contracts negotiated in the future.

**Note 2 Net Loss Per Common Share**

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is computed by dividing the net loss applicable to common shareholders by the weighted-average number of unrestricted common shares and dilutive common share equivalents outstanding for the period, determined using the treasury-stock method and the as if-converted method.

The basic and diluted net loss per common share amounts for the three and six months ended June 30, 2010 and 2009 were computed based on the shares of common stock outstanding during the respective periods. The net loss per share for the three and six months ended June 30, 2010 includes the full effect of the 6,820,000 common shares issued in our initial public offering in the fourth quarter of 2009 and the conversion of our convertible preferred stock into 11,514,508 shares of common stock upon completion of the offering. As a result of the issuance of these common shares during the fourth quarter of 2009, there is a lack of comparability in the basic and diluted net loss per share amounts for the three and six months ended June 30, 2010 and 2009. The following table presents the computation of basic and diluted net loss per common share (in thousands, except share and per share data):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
<b>Historical</b>				
<b>Numerator:</b>				
Net loss	\$ (7,804)	\$ (6,109)	\$ (14,465)	\$ (11,591)
<b>Denominator:</b>				
Weighted-average common shares outstanding	21,381,216	2,953,074	21,337,556	2,953,494
Less: Weighted-average unvested common shares subject to repurchase		(23,384)		(24,097)
Denominator for basic and diluted net loss per common share	21,381,216	2,929,690	21,337,556	2,929,397
Basic and diluted net loss per common share	\$ (0.36)	\$ (2.09)	\$ (0.68)	\$ (3.96)

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

	<b>June 30,</b>	
	<b>2010</b>	<b>2009</b>
Convertible preferred stock		11,514,506
Outstanding options to purchase common stock	3,560,260	2,819,594
Warrants to purchase common stock and convertible preferred stock	209,017	234,230
Common stock subject to repurchase		23,385
Total	3,769,277	14,591,715

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

As of December 31, 2009, our investment portfolio was made up of cash and cash equivalents and mortgage-backed, adjustable-rate securities issued by, or fully collateralized by, the U.S. government or U.S.

government-sponsored entities. In May 2010 we sold the mortgage-backed securities and invested the proceeds in cash and cash equivalent funds. All investments are classified as short-term and available-for-sale on the accompanying balance sheets.

We owned zero and two securities with unrealized loss positions as of June 30, 2010 and December 31, 2009, respectively. The two securities with the unrealized loss positions as of December 31, 2009 were immaterial and were not other-than-temporarily impaired. We assessed the fundamentals of these securities to identify their individual sources of risk and potential for other-than-temporary impairment. The assessment included a review of performance indicators of the underlying assets in the security, loan-to-collateral value ratios, third-party guarantees, vintage, geographic concentration, industry analyst reports, sector credit ratings, volatility of the security's fair value, current market liquidity,

**Table of Contents**

reset indices, prepayment levels, credit rating downgrades and the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment.

The composition of our investment income is as follows:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
	<b>(in thousands)</b>			
Gross interest income	\$ 48	\$ 63	\$ 71	\$ 150
Gross realized gains on investments	3		3	
Gross realized losses on investments	(30)	(2)	(36)	(8)
Total investment income	\$ 21	\$ 61	\$ 38	\$ 142

Realized gains and losses on sales of investments are calculated based on the specific identification method and related primarily to the sale of mortgage-backed securities.

**Note 4 Fair Value Measurements**

The accounting standard for fair value measurements provides a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. Under this standard, 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.

In May 2010 we sold our remaining mortgage-backed securities and invested the proceeds in cash and cash-equivalent funds. This sale represented a transfer of the \$3.0 million in Level 2 investments on hand at December 31, 2009 to Level 1 investments as of June 30, 2010. Our fair value hierarchy for our financial assets and liabilities measured at fair value on a recurring basis is as follows:

	<b>June 30, 2010</b>		
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
	<b>(in thousands)</b>		
			<b>Total</b>
Assets:			
Money market funds	\$ 3,066	\$	\$ 3,066
Money market funds classified as short term investments	39,010		39,010
Total	\$ 42,076	\$	\$ 42,076

	<b>December 31, 2009</b>		
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
	<b>(in thousands)</b>		
			<b>Total</b>
Assets:			
Money market funds	\$ 57,073	\$	\$ 57,073

Edgar Filing: OMEROS CORP - Form 10-Q

Mortgage-backed securities		2,979		2,979
Total	\$ 57,073	\$ 2,979	\$	\$ 60,052

Cash of \$446,000 is excluded in our fair value hierarchy disclosure as of December 31, 2009. Additionally, the fair value hierarchy disclosure includes restricted cash of \$193,000 as of June 30, 2010 and December 31, 2009. Unrealized gains and losses of \$0 and \$41,000 as of June 30, 2010 and December 31, 2009, respectively, are associated with our short-term investments and are included in accumulated other comprehensive income in the accompanying balance sheets.

**Table of Contents****Note 5 Certain Balance Sheet Accounts***Accrued Expenses*

Accrued expenses consisted of the following:

	<b>June 30, 2010</b>	<b>December 31, 2009</b>
	<b>(in thousands)</b>	
Clinical trials	\$ 1,850	\$ 1,868
Contract preclinical research	111	60
Employee compensation	620	324
Other accruals	686	585
Accrued expenses	\$ 3,267	\$ 2,837

*Comprehensive Loss*

Comprehensive loss is comprised of net loss and certain changes in equity that are excluded from net loss. Our only component of comprehensive loss is unrealized gains (losses) on available-for-sale securities. There were no unrealized gains (losses) as of June 30, 2010 as we sold the underlying available-for-sale securities during May 2010. The components of comprehensive loss are as follows:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
	<b>(in thousands)</b>			
Net loss	\$ (7,804)	\$ (6,109)	\$ (14,465)	\$ (11,591)
Unrealized gain on available-for-sale securities		63		155
Comprehensive loss	\$ (7,804)	\$ (6,046)	\$ (14,465)	\$ (11,436)

**Note 6 Revenue**

We have received Small Business Innovative Research, or SBIR, grants from the National Institutes of Health totaling \$3.9 million and \$3.2 million through June 30, 2010 and December 31, 2009, respectively. The purpose of the grants is to support the research and development of our product candidates. For the three months ended June 30, 2010 and 2009 and for the six months ended June 30, 2010 and 2009, we recorded revenue related to these grants of \$327,000, \$102,000, \$610,000 and \$123,000, respectively. As of June 30, 2010, \$804,000 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. The funding is expected to advance our PDE10 program through the completion of Phase 1 clinical trials. Under the agreement, we may receive grant and equity funding of up to \$9.0 million upon achievement of research milestones. We hold the exclusive rights to the technology. In consideration for SMRI's grant funding, we may 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. As of June 30, 2010 and December 31, 2009, we have received a total of \$5.7 million from SMRI. As of June 30, 2010, amounts included in the accompanying balance sheet pertaining to this agreement included \$478,000 in deferred revenue and \$3.2 million from the sale of 255,103 shares of Series E convertible preferred stock, which were recorded at their estimated fair value and subsequently converted to common stock upon the completion of the initial public offering. For the three months ended June 30, 2010 and 2009 and for

the six months ended June 30, 2010 and 2009, we recognized revenue under this agreement of \$129,000, \$135,000, \$224,000 and \$231,000, respectively.

In May 2010, we entered into an agreement with The Michael J. Fox Foundation, or MJFF, to provide funding for a study of PDE7 inhibitors for the treatment of Parkinson's disease. The agreement is for a six-month period and provides funding of actual costs incurred up to a total of \$76,000. In consideration of MJFF's grant funding, MJFF will receive access to the study data results, subject to certain restrictions on data sharing. We hold and will continue to hold the



**Table of Contents**

exclusive rights to the technology and have no future obligation to MJFF for royalties or other monetary consideration resulting from the ongoing development of the technology. The funds are being recognized as revenue as the related expenses have been incurred. For the three months and six months ended June 30, 2010, we recognized revenue of \$41,000. Revenue of \$464,000 was recognized under a separate agreement with MJFF during 2009.

**Note 7 Commitments and Contingencies**

In connection with the funding agreement with SMRI, beginning the first calendar year after commercial sales of a schizophrenia product, if and when a product is commercialized, we may become obligated to pay royalties based on net income, as defined in the agreement, not to exceed a set multiple of total grant funding received. Based on the amount of grant funding received as of June 30, 2010, the maximum amount of royalties payable by us is \$12.8 million. We have not paid any such royalties through June 30, 2010.

In July 2008, we entered into a discovery and development agreement with Affitech AS, or Affitech, to isolate and optimize fully human antibodies for our mannan-associated serine protease-2, or MASP-2, program. Under the terms of the agreement, Affitech applied its human antibody libraries and proprietary antibody discovery and screening technologies to generate fully human MASP-2 antibodies for us. In March 2010, we amended the antibody development agreement with Affitech. Under the terms of the amendment, Affitech released us from any future obligations to make royalty or milestone payments in exchange for \$500,000. The agreement also stipulates that we can request certain optional services for a fee. The agreement may be terminated for cause by either party, or at any time by us by providing 30 day advance written notice to Affitech. For the three months ended June 30, 2010 and 2009 and for the six months ended June 30, 2010 and 2009, we recognized research and development expense under this agreement of \$0, \$0, \$500,000 and \$200,000, respectively.

In September 2008, we entered into a technology option agreement with Patobios Limited, or Patobios, to evaluate and potentially acquire the intellectual property rights covering Patobios G protein-coupled receptor, or 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. In December 2009, we exercised our right to extend the third option period from January 2010 to June 2010 at a cost to us of \$542,000 CAD (\$516,000 USD). 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 \$500,000 CAD (\$487,000 USD). For the three months ended June 30, 2010 and 2009 and for the six months ended June 30, 2010 and 2009, we recognized research and development expense under this agreement of \$487,000, \$471,000, \$497,000 and \$471,000, respectively. Under the terms of the agreement, we have the exclusive option to acquire the intellectual property rights, including patents, covering Patobios GPCR technology at any time during any of the option periods for a total acquisition price of \$10.8 million CAD in cash and stock. In addition, if we achieve the de-orphanization milestone, we will be required to pay Patobios a \$500,000 CAD milestone payment that would be credited against the cash portion of the \$10.8 million CAD purchase price. Also, following achievement of the de-orphanization milestone, we will be required to purchase the GPCR technology from Patobios for the \$10.8 million CAD purchase price if, during the term of the agreement, the sum of the following items is at least equal to \$5.1 million CAD: (a) the amount paid by us to Patobios from licenses granted by us to third parties for the development and commercialization of the de-orphanized GPCRs, (b) the amount of any government or non-profit funding received by us specifically allocated for the purchase of the GPCR technology and (c) the \$500,000 CAD de-orphanization milestone payment. In June 2010, we successfully identified compounds that interact with, and modulate signaling of, three orphan G protein-coupled receptors linked to cancer, metabolic disorders and appetite control; however, this success has not triggered the de-orphanization milestone as defined in the agreement. The agreement may be terminated for cause by either party, at any time by mutual consent of us and Patobios, or by us at any time prior to the achievement of the de-orphanization milestone.

In October 2008, we entered into an antibody development agreement with North Coast Biologics LLC, or North Coast, to isolate and optimize antibodies for our MASP-2 program. Under the terms of the agreement, North Coast will apply its proprietary antibody discovery and screening technologies to generate MASP-2 antibodies for us. We recorded no research and development expense under this agreement during the three months ended June 30, 2010 and 2009 and the six months ended June 30, 2010 and 2009, respectively. Under the agreement, we may be required to make additional payments to North Coast of up to \$4.0 million upon the achievement of certain development events,

such as initiation of clinical trials and the receipt of marketing approval for a drug product containing an antibody developed by North Coast.

**Table of Contents**

The agreement also provides us with an option to have North Coast generate antibodies for additional targets. If this option is exercised, we may be required to make additional payments to North Coast for rights to the technology and milestone payments of up to \$4.1 million per selected target. In addition, we are obligated to pay North Coast a low single-digit percentage royalty on any of our net sales of drug products containing an antibody developed by North Coast under the agreement. The agreement may be terminated for cause by either party.

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 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. Under the agreement, we may be required to make payments of up to \$2.3 million 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.

On March 3, 2010, we entered into a license agreement with Daiichi-Sankyo Company, Limited (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. Under the agreement, we agreed to make milestone payments to Daiichi of up to \$23.5 million upon the achievement of certain events, such as successful completion of preclinical toxicology studies; dosing of human subjects in Phase 1, 2 and 3 clinical trials; receipt of marketing approval of a PDE7 inhibitor product; and reaching specified sales milestones. 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 received by us from the sublicensee. For the three and six months ended June 30, 2010, we recognized research and development expense under this agreement of \$0 and \$25,000.

On April 23, 2010, we entered into an Exclusive License Agreement with Helion Biotech ApS, or Helion, pursuant to which we received a royalty bearing, worldwide exclusive license in and to all of Helion's intellectual property rights related to 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 and agreed to make development and sales milestone payments to Helion of up to an additional \$6.85 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. For the three and six months ended June 30, 2010, we recognized research and development expense under this agreement of \$519,000 and \$529,000, respectively.

**Note 8 Stock-Based Compensation***Stock Options*

In 2008, our board of directors adopted and the shareholders approved the 2008 Equity Incentive Plan, or 2008 Plan. The 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. 892,857 shares of common stock were initially reserved for issuance under the 2008 Plan. The 2008 Plan also allows any shares returned under our Amended and Restated 1998 Stock Option Plan, or 1998 Plan, as a result of cancellation of options or repurchase of shares issued pursuant to the 1998 Plan, to be issued under the 2008 Plan subject to a maximum limit of 3,084,848 shares. As of June 30, 2010 and December 31, 2009, a total of 352,323 and 321,528 shares, respectively, have been reserved under the 2008 Plan as a result of the cancellation of options or repurchase of shares under the 1998 Plan. In addition, the 2008 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year, beginning with

the 2010 fiscal year, equal to the lesser of:

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

**Table of Contents**

1,785,714 shares; and

such other amount as our board of directors may determine.

On January 1, 2010, in accordance with the 2008 Plan annual increase provisions, the authorized shares in the 2008 Plan increased by 1,064,279.

A summary of stock option activity and related information follows:

	<b>Shares Available for Grant</b>	<b>Options Outstanding</b>	<b>Weighted- Average Exercise Price per Share</b>
Balance at December 31, 2009	1,013,256	2,847,549	\$ 1.94
Authorized increase in 2008 Plan shares	1,095,074		
Expired	(30,795)		
Granted	(1,018,185)	1,018,185	6.15
Exercised		(148,914)	1.07
Cancelled	156,560	(156,560)	9.85
Balance at June 30, 2010	1,215,910	3,560,260	\$ 2.84

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. The estimated per share weighted-average fair value of stock options granted to employees during the six months ended June 30, 2010 was \$4.20.

As stock-based compensation expense is based on options ultimately expected to vest, the expense has been reduced for estimated forfeitures. The fair value of each employee option grant was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Expected volatility	77%	75%	77%	71% - 75%
Expected term (in years)	6.08	6.08	6.08	6.08
Risk-free interest rate	2.45%	2.64%	2.45% - 2.77%	2.13% - 2.64%
Expected dividend yield	0%	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:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
	<b>(in thousands)</b>			
Research and development	\$ 81	\$ 217	\$ 378	\$ 437
General and administrative	446	274	622	502
Total	\$ 527	\$ 491	\$ 1,000	\$ 939

In connection with the non-employee options, we recognized expense of \$33,000, \$97,000, \$52,000 and \$154,000 for the three months ended June 30, 2010 and 2009 and for the six months ended June 30, 2010 and 2009, respectively.

**Note 9 Related-Party Transactions**

We conduct research using the services of one of our founders, Pamela Pierce Palmer, M.D., Ph.D. In 2007, we granted Dr. Palmer an option to purchase 20,408 shares of common stock and recognized \$13,000, \$25,000, \$21,000 and \$39,000 of non-cash compensation associated with this option for the three months ended June 30, 2010 and 2009 and for the six months ended June 30, 2010 and 2009, respectively.

## **Table of Contents**

### **Note 10 Subsequent Events**

In July 2010, 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 price per share over 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 4.00% to 7.00%, based on a minimum price that we solely 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 4,297,495 shares in connection with the committed equity line financing facility.

In partial consideration for Azimuth's execution and delivery of the Purchase Agreement, we paid to Azimuth upon the execution and delivery of the Purchase Agreement \$100,000 in cash. We have also agreed to pay \$35,000 of Azimuth's legal fees and expenses. No additional legal fees incurred by Azimuth are payable by us in connection with any sale of shares to Azimuth.

We also entered into a placement agent agreement with Reedland Capital Partners, in connection with the financing facility. We have agreed to pay Reedland, upon each sale of our common stock to Azimuth under the Purchase Agreement, a fee equal to 0.5% of the aggregate dollar amount of common stock purchased by Azimuth upon settlement of each such sale.

## **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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, 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:*

*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 ability to release the results from our ongoing Phase 3 clinical program of OMS103HP for ACL reconstruction surgery by year-end 2010;*

*our ability to market OMS103HP by 2012, at the earliest;*

*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 de-orphanization of orphan 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 general and administrative expenses;*



## **Table of Contents**

*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; 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 this Quarterly Report on Form 10-Q under the heading Risk Factors and in our other filings with the Securities and Exchange Commission. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. 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 future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, 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 focused on inflammation 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 five ongoing clinical development programs, including four from our PharmacoSurgery platform and one from our Addiction program. Our most advanced clinical development program is in a Phase 3 clinical program. In addition, we have leveraged our expertise in inflammation and the central nervous system to build a deep and diverse pipeline of preclinical programs targeting large markets 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.

OMS103HP, our lead PharmacoSurgery product candidate, is in two clinical programs. The first is a Phase 3 clinical program evaluating OMS103HP's safety and ability to improve postoperative joint function and reduce pain following arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery. The second program is preparing for Phase 3 clinical trials to evaluate OMS103HP's safety and ability to improve postoperative joint function and reduce pain following arthroscopic partial meniscectomy surgery. We expect to release the results from our ongoing Phase 3 clinical program for ACL reconstruction surgery by year-end 2010. 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.

Our other current PharmacoSurgery product candidates are OMS302, being developed for use during ophthalmological procedures, including cataract and other lens replacement surgery, and OMS201, being developed for use during urological surgery, including uroendoscopic procedures. We are conducting a Phase 2b clinical trial for OMS302 to assess the effect of the mydriatic API and the anti-inflammatory API in a full-factorial design. A Phase 1/Phase 2 clinical trial of OMS201 is underway in patients undergoing ureteroscopic removal of ureteral or renal stones.

**Table of Contents**

In addition to our PharmacoSurgery platform, we have a deep and diverse pipeline of additional product development programs targeting large market opportunities in inflammation and the CNS covered by a broad intellectual property portfolio. In our Addiction program, we are developing proprietary compositions that include peroxisome proliferator-activated receptor gamma, or PPAR $\gamma$ , agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine, alcohol and amphetamines, as well as other compulsive behaviors. The National Institute on Drug Abuse is funding substantially all of the costs of a Phase 2 clinical study evaluating a PPAR $\gamma$  agonist in the treatment of addiction to opioids. This Phase 2 clinical study is being conducted by researchers at the New York State Psychiatric Institute.

In our mannan-binding lectin-associated serine protease-2, or MASP-2, program, we are developing proprietary MASP-2 antibody therapies to treat disorders caused by complement-activated inflammation. In our PDE10 program, we are developing proprietary compounds to treat schizophrenia and other psychotic disorders. Our PDE7 program is based on our demonstration of a previously unknown link between PDE7 and any movement disorder, such as Parkinson's disease and Restless Legs Syndrome, and we are developing proprietary compounds for the treatment of these and other movement disorders. In our GPCR program, we believe that we have the capability to complete high-throughput de-orphanization of orphan GPCRs, or the identification of synthetic molecules that bind the receptors, and to develop product candidates that act at these new potential drug targets. In June 2010, we successfully identified compounds that interact with, and modulate signaling of, three orphan GPCRs linked to cancer, metabolic disorders and appetite control.

We have incurred significant losses since our inception. As of June 30, 2010, our accumulated deficit was \$132.8 million and total shareholders' equity was \$29.8 million. We recognized net losses of \$7.8 million, \$6.1 million, \$14.5 million and \$11.6 million for the three months ended June 30, 2010 and 2009, and for the six months ended June 30, 2010 and 2009, respectively. These losses have resulted principally from expenses incurred in connection with research and development activities, consisting primarily of preclinical studies, clinical trials and manufacturing services associated with our current product candidates. Compared to 2009, we expect our net losses in 2010 to increase as we continue to advance our clinical trials, expand our research and development efforts and add personnel as well as laboratory and office space for our anticipated growth.

*Revenue*

We have recognized \$5.7 million of revenue from inception (June 16, 1994) through June 30, 2010, consisting of grant funding from third parties. Other than grant funding, we do not expect to receive any revenue from our product candidates until we receive regulatory approval and commercialize the products or until we potentially enter into collaborative agreements with third parties for the development and commercialization of our product candidates. We continue to pursue government and private grant funding for our product candidates and research programs. If our development efforts for any of our product candidates result in clinical success and regulatory approval or collaboration agreements with third parties, we could generate revenue from those product candidates.

*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 trials 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 as 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 and clinical trial sites;

**Table of Contents**

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

third-party supplier expenses including laboratory and other supplies.

Our internal resources, employees and infrastructure are not directly tied to any individual research project and are typically deployed across multiple projects. Through our clinical development programs, we are advancing our product candidates in parallel for multiple therapeutic indications and, through our preclinical development programs, we are seeking to develop potential product candidates for additional disease indications. Due to the number of ongoing projects and our ability to utilize resources across several projects, we do not record or maintain information regarding the costs incurred for our research and development programs on a program-specific basis.

Research and development expenses since inception to June 30, 2010 were \$90.4 million. Our research and development expenses can be divided into clinical research and development and preclinical research and development activities. The following table illustrates our expenses associated with these activities:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
	<b>(in thousands)</b>			
<b>Clinical Research and Development</b>				
Salaries, benefits and related costs	\$ 886	\$ 989	\$ 1,704	\$ 1,911
Clinical Trials	719	610	1,076	1,162
Manufacturing services, consulting, laboratory supplies, and other costs	1,386	380	2,322	712
Other costs	260	292	538	576
Stock-based compensation	43	129	203	259
Total Clinical Research and Development Expenses	3,294	2,400	5,843	4,620
<b>Preclinical Research and Development</b>				
Salaries, benefits and related costs	917	647	1,650	1,331
Research and preclinical studies, consulting, laboratory supplies, and other costs	1,556	1,052	2,840	1,711
Other costs	316	390	694	759
Stock-based compensation	37	88	175	178
Total Preclinical Research and Development Expenses	2,826	2,177	5,359	3,979
Total Research and Development Expenses	\$ 6,120	\$ 4,577	\$ 11,202	\$ 8,599

Clinical research and development costs consist of clinical trials, manufacturing services, regulatory activities and related personnel costs, and other costs such as rent, utilities, depreciation and stock-based compensation. Preclinical research and development costs consist of our research activities, preclinical studies, related personnel costs and laboratory supplies, and other costs such as rent, utilities, depreciation and stock-based compensation.

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. We expect our research and development expenses to increase in the future as we continue the advancement of our clinical trials and preclinical product development programs.

## **Table of Contents**

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 expense 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 2012, 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, 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. We expect our general and administrative expenses to increase in the future as we add additional employees and facilities to support our anticipated growth as a public company.

### *Interest Expense*

Interest expense consists of interest on our notes payable and the amortization of the related discount.

### *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 and changes in the fair value of our preferred stock warrant liability.

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

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of any contingent assets and liabilities at the date of the financial statements, as well as reported revenue and expenses during the reporting periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. 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 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 management judgment and estimates about matters that are uncertain:

revenue recognition;

research and development expenses, primarily clinical trial expenses;

stock-based compensation;

preferred stock warrant liability; and

fair value measurement of financial instruments.

**Table of Contents**

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. We recognize grant funding as revenue when the related qualified research and development expenses are incurred up to the limit of the approved funding amounts.

The accounting standard for revenue provides 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, contract research organizations 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; and third-party supplier expenses including laboratory and other supplies. 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 accrual; these changes in estimates may result in understated or overstated expenses at a given point in time. To date, our estimates have not differed significantly from actual costs. Internal research and development expenses are expensed as incurred. Third-party research and development expenses are expensed at the earlier of when the contracted work has been performed or as upfront and milestone payments are made.

**Stock-Based Compensation**

We account for stock-based compensation under applicable accounting standards, which requires that the measurement and recognition of compensation expense for all future share-based payments made to employees and directors be based on estimated fair values. We are using the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. We estimate the fair value of our share-based awards to employees and directors using the Black-Scholes option-valuation model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs.

As stock-based compensation expense is based on options ultimately expected to vest, the expense has been reduced for estimated forfeitures. The fair value of each employee option grant was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions during the years ended:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Expected volatility	77%	75%	77%	71% - 75%
Expected term (in years)	6.08	6.08	6.08	6.08
Risk-free interest rate	2.45%	2.64%	2.45% - 2.77%	2.13% - 2.64%
Expected dividend yield	0%	0%	0%	0%

## **Table of Contents**

*Expected Volatility.* The expected volatility rate used to value stock option grants is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical and biotechnology industry in a similar stage of development.

*Expected Term.* We elected to utilize the simplified method for plain vanilla options to value stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

*Risk-free Interest Rate.* The risk-free interest rate assumption was based on zero-coupon U.S. Treasury instruments that had terms consistent with the expected term of our stock option grants.

*Expected Dividend Yield.* We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future.

Stock-based compensation guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. 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.

### *Fair Value Measurement of Financial Instruments*

Our financial assets and liabilities are measured at fair value, 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.

In determining the fair value of our financial assets and liabilities, we used various valuation approaches. The guidance establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources such as quotes in active markets. Unobservable inputs are those in which little or no market data exists and reflect our assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment.

Whenever the estimated fair value of any of our available-for-sale securities is less than their related cost, we perform an impairment analysis to determine the classification of the impairment as temporary or

other-than-temporary. A temporary impairment results in an unrealized loss being recorded in the other comprehensive income component of shareholders' equity. Such an unrealized loss does not affect net loss for the applicable accounting period. However, an other-than-temporary impairment charge is recorded as a realized loss in the consolidated statement of operations and increases net loss for the applicable accounting period. The primary factors we consider to differentiate our impairments between temporary and other-than-temporary impairments include the length of the time and the extent to which the market value has been less than cost, the financial condition and near-term prospects of the issuer and our intent and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

## **Table of Contents**

We believe that the values assigned to our available-for-sale securities as of June 30, 2010 and December 31, 2009 are fairly stated in accordance with GAAP and are based upon reasonable estimates and assumptions. In addition, we believe that the cost basis for our available-for-sale securities are recoverable in all material respects.

### **Results of Operations**

#### *Comparison of Three Months Ended June 30, 2010 and June 30, 2009*

**Revenue.** Revenue was \$497,000 for the three months ended June 30, 2010 compared with \$371,000 for the three months ended June 30, 2009. The increase was primarily due to our recognition of additional revenue in connection with grants from the National Institutes of Health, or NIH, and was partially offset by a decrease in revenue recognized from a grant from The Michael J. Fox Foundation, or the MJFF, for our PDE7 program.

**Research and Development Expenses.** Research and development expenses were \$6.1 million for the three months ended June 30, 2010 compared with \$4.6 million for the three months ended June 30, 2009. The increase was due primarily to higher contract service and consulting costs associated with several of our clinical and preclinical programs and an accrual for employee benefits under our annual cash bonus program. This increase also included a one-time payment of \$500,000 to Helion Biotech ApS, or Helion, for an exclusive license to intellectual property rights for our MASP-2 program.

**General and Administrative Expenses.** General and administrative expenses were \$2.0 million for the three months ended June 30, 2010 compared with \$1.5 million for the three months ended June 30, 2009. The increase was primarily due to higher costs associated with being a public company and an accrual for employee benefits under our annual cash bonus program, offset by a decrease in patent costs.

**Investment Income.** Investment income was \$21,000 for the three months ended June 30, 2010 compared with \$61,000 for the three months ended June 30, 2009. The decrease was due primarily to lower market rates.

**Interest Expense.** Interest expense was \$409,000 for the three months ended June 30, 2010 compared with \$575,000 for the three months ended June 30, 2009. The decrease was primarily due to lower interest paid on our notes payable to BlueCrest Venture Finance Master Fund Limited, or BlueCrest, due to a lower principal balance.

**Other Income (Expense).** Other income was \$218,000 for the three months ended June 30, 2010 compared with \$86,000 for the three months ended June 30, 2009. The increase was primarily due to the change in fair value of warrants partially offsetting sublease income for the three months ended June 30, 2009. Upon completion of our IPO in October 2009, all of our preferred stock warrants were converted into common stock warrants, resulting in the reclassification of the preferred stock warrant liability to equity and no further requirement for us to record the change in fair value of the warrants.

#### *Comparison of Six Months Ended June 30, 2010 and June 30, 2009*

**Revenue.** Revenue was \$875,000 for the six months ended June 30, 2010 compared with \$568,000 for the six months ended June 30, 2009. The increase was primarily due to our recognition of additional revenue in connection with grants from the NIH, and was partially offset by a decrease in revenue recognized from a grant from the MJFF for our PDE7 program.

**Research and Development Expenses.** Research and development expenses were \$11.2 million for the six months ended June 30, 2010 compared with \$8.6 million for the six months ended June 30, 2009. The increase was due primarily to higher contract service and consulting costs associated with several of our clinical and preclinical programs, and an accrual for employee benefits under our annual cash bonus program. This increase also included a one-time payment of \$500,000 to Helion for an exclusive license to intellectual property rights for our MASP-2 program, and a one-time



## **Table of Contents**

payment to Affitech AS of \$500,000 in exchange for its agreement to release us from any future obligations to make royalty or milestone payments under our MASP-2 antibody development agreement.

*General and Administrative Expenses.* General and administrative expenses were \$3.7 million for the six months ended June 30, 2010 compared with \$2.9 million for the six months ended June 30, 2009. The increase was primarily due to higher costs associated with being a public company and an accrual for employee benefits under our annual cash bonus program, offset by a decrease in patent costs.

*Investment Income.* Investment income was \$38,000 for the six months ended June 30, 2010 compared with \$142,000 for the six months ended June 30, 2009. The decrease was due primarily to lower market rates.

*Interest Expense.* Interest expense was \$861,000 for the six months ended June 30, 2010 compared with \$1.2 million for the six months ended June 30, 2009. The decrease was primarily due to lower interest paid on our notes payable to BlueCrest due to a lower principal balance.

*Other Income (Expense).* Other income was \$417,000 for the six months ended June 30, 2010 compared with \$348,000 for the six months ended June 30, 2009. The increase was primarily due to the higher non-cash income from the change in fair value of warrants partially offsetting sublease income for the three months ended June 30, 2009. Upon completion of our IPO in October 2009, all of our preferred stock warrants were converted into common stock warrants, resulting in the reclassification of the preferred stock warrant liability to equity and no further requirement for us to record the change in fair value of the warrants.

## **Liquidity and Capital Resources**

Since inception, we have financed our operations primarily through private and public placements of equity securities for proceeds totaling \$139.2 million and through a debt facility with loan proceeds totaling \$17.0 million. The proceeds have been used to fund our operations.

As of June 30, 2010, we had \$41.9 million in cash, cash equivalents and short-term investments. Our cash, cash equivalents and short-term investment balances are held in a variety of 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.

*Operating activities.* Net cash used in operating activities of \$15.2 million for the six months ended June 30, 2010 was primarily due to the net loss for the period of \$14.5 million and changes in operating assets and liabilities of \$2.1 million, offset in part by \$1.0 million of non-cash stock-based compensation. Net cash used in operating activities of \$10.0 million for the six months ended June 30, 2009 was primarily due to the net loss of \$11.6 million, offset in part by \$939,000 of non-cash stock-based compensation expense and \$227,000 from changes in operating assets and liabilities.

*Investing activities.* Net cash provided by investing activities was \$19.8 million for the six months ended June 30, 2010 primarily due to the proceeds from the sale of investments during the period. Net cash used in investing activities was \$1.7 million for the six months ended June 30, 2009 primarily due to the purchase of investments in the amount of \$3.2 million, offset by proceeds from the sale and maturities of investments of \$1.5 million during the period.

*Financing activities.* Net cash used in financing activities was \$2.6 million for the six months ended June 30, 2010 primarily as a result of principal payments under our notes payable to BlueCrest. Net cash provided by financing activities was \$277,000 for the six months ended June 30, 2009 primarily due to the proceeds from issuance of convertible preferred stock to The Stanley Medical Research Institute, or SMRI, offset by principal payments under the notes payable to BlueCrest.

**Table of Contents**

In July 2010, 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 price per share over 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 4.00% to 7.00%, based on a minimum price that we solely 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 4,297,495 shares in connection with the committed equity line financing facility.

In partial consideration for Azimuth's execution and delivery of the purchase agreement for the facility, we paid to Azimuth \$100,000 in cash. We also paid \$35,000 of Azimuth's legal fees and expenses. No additional legal fees incurred by Azimuth are payable by us in connection with any sale of shares to Azimuth.

We also entered into a placement agent agreement with Reedland Capital Partners, in connection with the financing facility. We have agreed to pay Reedland, upon each sale of our common stock to Azimuth, a fee equal to 0.5% of the aggregate dollar amount of common stock purchased by Azimuth upon settlement of each such sale.

As of June 30, 2010, our notes payable balance was \$10.1 million, consisting primarily of notes payable to BlueCrest. We have classified \$4.9 million of the \$10.1 million balance of notes payable to BlueCrest as a long-term liability. We cannot borrow any additional amounts under the BlueCrest agreement. Interest on amounts borrowed under the loan agreement accrues at an annual rate of 12.5%. Payments due under each tranche were interest only for the first three months, and are interest and principal thereafter for 36 months. Under the loan agreement, we must comply with affirmative and negative covenants and, if any event, condition or change occurs that has a material adverse effect (as defined in the agreement), BlueCrest may require immediate repayment of all loan amounts then currently outstanding. We have no indication that we are in default of the material adverse effect clause, and no scheduled loan payments have been accelerated as a result of this provision. We are using the proceeds of the loan for working capital, capital expenditures and general corporate purposes. Our obligations under the loan agreement are collateralized by substantially all of our assets, other than intellectual property. We may prepay the outstanding principal amount of all loans then outstanding in whole, but not in part, by providing 30 days written notice. However, a prepayment premium of 2.0% applies if the prepayment is made within 18 months after the borrowing date of the applicable tranche. If a prepayment is made more than 18 months after the date of the applicable tranche, then the prepayment premium is reduced to 1.0%. In connection with the loan and security agreement, we incurred debt issuance costs of \$122,000.

As a condition to BlueCrest making the initial \$5.0 million loan, we agreed to pay a success fee to BlueCrest in an amount up to \$400,000 prorated based on amounts borrowed should certain exit events, such as an initial public offering, occur prior to September 12, 2018. Following the completion of our initial public offering in October 2009, we paid BlueCrest a success fee in the amount of \$340,000. We have no further obligations to pay a success fee to BlueCrest.

In connection with the execution of the loan and security agreement, we issued a warrant to BlueCrest to purchase 25,213 shares of our common stock at an exercise price of \$13.48 per share. This warrant expired upon the closing of our initial public offering in October 2009 without being exercised.

In December 2006, we entered into a funding agreement with 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 June 30, 2010, we had received \$5.7 million from SMRI, \$1.8 million of which was recorded as revenue, \$3.2 was recorded as equity funding and \$478,000 remains in deferred revenue.



**Table of Contents**

In May 2010, we entered into an additional agreement with the MJFF to provide funding for a study of PDE7 inhibitors for the treatment of Parkinson's disease. The agreement was for a six-month period and provides funding of actual costs incurred up to a total of \$76,000. We received an advance payment of \$38,000 in July 2010.

*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 have based 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 OMS103HP, OMS302, OMS201 and our Addiction program;

costs related to manufacturing services;

whether the hiring of a number of new employees to support our continued growth during this period will occur at salary levels consistent with our estimates;

the scope, rate of progress, results and costs of our preclinical testing, clinical trials and other research and development activities for additional 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, Limited, Helion Biotech, ApS and North Coast Biologics;

market acceptance of our approved products;

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 any of these types of transactions other than our right to acquire assets for our GPCR program from Patobios Limited for \$10.8 million CAD in cash and stock;

whether we receive grant funding for our programs;

our degree of success in commercializing OMS103HP and other product candidates; and

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



## **Table of Contents**

We do not anticipate generating revenue from the sale of our product candidates until 2012 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 Opportunity, Ltd., we currently do not have any commitments for future external 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.

## **Contractual Obligations and Commitments**

There have been no significant changes during the six months ended June 30, 2010 to the items that we disclosed as our contractual obligations and commitments in our Form 10-K for the year ended December 31, 2009, except as follows: 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 and agreed to make development and sales milestone payments to Helion of up to an additional \$6.85 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.

## **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 June 30, 2010, we had cash, cash equivalents and short-term investments of \$41.9 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 June 30, 2010. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2010, 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) of 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**

On September 21, 2009, our former chief financial officer, Richard J. 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. We are vigorously defending ourselves against Mr. Klein's claims and to seek, among other things, our attorneys' fees and costs incurred in defending this action.

In December 2008, Mr. 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 these grant matters. 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.

**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.*

**Table of Contents**

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

**Our success largely depends on the success of our lead PharmacoSurgery™ product candidate, OMS103HP, and we cannot be certain that it will receive regulatory approval or be successfully commercialized. If we are unable to commercialize OMS103HP, or experience significant delays in doing so, our business will 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 will continue to incur, significant costs relating to the clinical development and commercialization of our lead product candidate, OMS103HP, for use during arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery as well as arthroscopic partial meniscectomy surgery. We have not yet obtained regulatory approval to market this product candidate for ACL reconstruction surgery, arthroscopic partial meniscectomy surgery or any other indication in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize this product candidate successfully. There can be no assurance that the data will be positive from any of our clinical trials of OMS103HP, including our Phase 3 clinical program evaluating OMS103HP in ACL reconstruction surgery. Even if the data are positive, the FDA may decide that our data are insufficient for approval of OMS103HP and require additional preclinical, clinical or other studies. If OMS103HP does not receive regulatory approval for ACL reconstruction surgery or arthroscopic partial meniscectomy surgery or if approval is delayed beyond our current expectations, or if it is not successfully commercialized for one or both uses, 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 do not know whether our clinical trials for OMS103HP will be completed on schedule or result in regulatory approval or in a marketable product. If approved for commercialization, we do not anticipate that OMS103HP will reach the market until 2012 at the earliest.

**Our success is also dependent on the success of our additional PharmacoSurgery product candidates, OMS302 and OMS201, and we cannot be certain that either will advance through clinical testing, receive regulatory approval or be successfully commercialized.**

In addition to OMS103HP, our success will depend on the successful commercialization of one or both of two additional PharmacoSurgery product candidates, OMS302 and OMS201. We are conducting a Phase 2b clinical trial for OMS302 to assess the effects of the mydriatic API and the anti-inflammatory API in a full-factorial design and a Phase 1/Phase 2 clinical trial evaluating the efficacy, safety and systemic absorption of OMS201 when used during ureteroscopy for removal of ureteral or renal stones. We have incurred and will continue to incur significant costs relating to the clinical development and commercialization of these PharmacoSurgery product candidates. We have not obtained regulatory approval to market 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 these product candidates successfully. If OMS302 and OMS201 do not receive regulatory approval, or if they are 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 do not know whether our planned and current clinical trials for OMS302 and OMS201 will be completed on schedule, if at all. In addition, we do not know whether any of our clinical trials will be successful or result in approval of either product for marketing.

**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 \$14.5 million and \$11.6 million for the six months ended June 30, 2010 and 2009, respectively. As of June 30, 2010, we had an accumulated deficit of approximately \$132.8 million. We expect to incur additional losses for at least the next several years and cannot be certain that we will ever achieve profitability. As a result, our business is subject to all of the risks inherent in the development of a new business enterprise, such as the risks that we may be unable to obtain additional capital needed to support the preclinical and clinical expenses of development



## **Table of Contents**

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.

**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 has questioned whether our studies evaluating OMS103HP in patients undergoing ACL reconstruction surgery are adequately designed to evaluate efficacy. If these studies fail to demonstrate efficacy, we will be required to provide additional information, including possibly the results of additional clinical trials. Also, 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**

**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;

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.

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 reexamination, 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 would make it difficult to raise additional capital. Many



## **Table of Contents**

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 and 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 ACL reconstruction surgery and begin related commercialization activities;

- initiate, conduct and complete the Phase 3 clinical trials of OMS103HP for use in arthroscopic partial meniscectomy surgery, should we elect to proceed with these Phase 3 clinical trials;

- conduct and complete the clinical trials of OMS302 for use during lens replacement surgery;

- conduct and complete the clinical trials of OMS201 for use in endoscopic surgery of the urological tract;

- continue our research and development;

- make milestone payments to our collaborators;

- make principal and interest payments due under our debt facility with BlueCrest Venture Finance Master Fund Limited, or BlueCrest;

- initiate and conduct clinical trials for other product candidates; and

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

In addition, if we elect under our Exclusive Technology Option Agreement with Patobios Limited to purchase assets for use in our GPCR program, we will be required to pay Patobios approximately \$10.8 million CAD, of which approximately \$7.8 million CAD is payable in cash and the remaining is payable in shares of our common stock.

Our clinical trials for OMS103HP may be delayed for many of the reasons discussed in these Risk Factors, which would increase the development expenses of OMS103HP and may require us to raise additional capital to complete the clinical development and commercialization of OMS103HP and to decrease spending on our other clinical and preclinical development programs.

**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.**

In 2008 we borrowed \$17.0 million pursuant to the terms of a loan and security agreement with BlueCrest and pledged substantially all of our assets, other than intellectual property, as collateral for this loan. Our agreement with BlueCrest 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 BlueCrest 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, BlueCrest may have the right to

## **Table of Contents**

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, BlueCrest'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 BlueCrest 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 BlueCrest's declaration through negotiation or litigation. Any declaration by BlueCrest 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 lead product candidate OMS103HP or future product candidates may never achieve market acceptance even if we obtain regulatory approvals.**

Even if we receive regulatory approvals for the commercial sale of our lead product candidate OMS103HP or future product candidates, 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.

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 lead product candidate OMS103HP or future 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

## **Table of Contents**

we are unable to increase market penetration of OMS103HP or our other 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 currently intend to rely solely on third parties to manufacture clinical and commercial supplies of all of our product candidates.**

We currently 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. Our clinical supplies of OMS103HP were manufactured in a freeze-dried, or lyophilized, form by Catalent Pharma Solutions, Inc. in its Albuquerque, New Mexico facility. In May 2008, Catalent

**Table of Contents**

announced that it sold this facility to OSO Biopharmaceuticals Manufacturing, LLC, or OSO, which continues to manufacture lyophilized drug products at this facility. We have not entered into a binding agreement with Catalent or OSO for the commercial supply of lyophilized OMS103HP, and cannot be certain that we will be able to do so on commercially reasonable terms. Qualification of any other facility to manufacture lyophilized OMS103HP would require transfer of manufacturing methods, the production of one or more additional registration batches of lyophilized OMS103HP and the generation of additional stability data, which could delay the availability of commercial supplies of lyophilized OMS103HP.

We have also formulated OMS103HP as a liquid solution and, if approved for marketing, intend to launch OMS103HP as a liquid solution. We have entered into an agreement with Hospira Worldwide, Inc. for the commercial supply of liquid OMS103HP. We do not believe that the inactive ingredients in liquid OMS103HP, which are included in the FDA's Inactive Ingredient Guide due to being present in drug products previously approved for parenteral use, impact its safety or effectiveness. The FDA will require us to provide comparative information and complete a stability study in connection with a potential NDA submission. We are currently conducting a nonclinical study to demonstrate that liquid OMS103HP is as safe as lyophilized OMS103HP; however, the FDA may require us to conduct additional studies. Delays, unexpected results in these studies or any requirement to conduct additional studies could delay the commercial availability of liquid OMS103HP. Any significant delays in the manufacture of clinical or commercial supplies could materially harm our business and prospects.

**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. Large-scale manufacturing processes have been developed only for lyophilized OMS103HP. For the liquid formulation of OMS103HP and our other product candidates, development of large-scale manufacturing processes 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





## Table of Contents

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 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 Company, Limited for our PDE7 program and we may use proprietary active ingredients in some of our future GPCR product candidates. We do not have licenses to any of the proprietary active ingredients we may elect to use in these potential future GPCR product candidates. 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 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 Biotech, ApS, or 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 \$6.85 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 MASP-2 program depends on third-party antibody developers and manufacturers.**

Any product candidates from our MASP-2 program would be antibodies and we do not have the internal capability to sequence, hybridize or clone antibodies or to produce antibodies for use in clinical trials or on a commercial scale. We have entered into development agreements with Affitech AS and North Coast Biologics for the development of MASP-2 antibodies; however, we do not have agreements in place with antibody manufacturers to manufacture clinical or commercial quantities of MASP-2 antibodies 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 antibody manufacturers. If we are unable to obtain clinical supplies of MASP-2 antibody product candidates, clinical trials or the development of any such product candidate 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.**

Any product candidates from our preclinical programs, including our MASP-2, PDE10, PDE7 and GPCR programs, must successfully complete preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before entering clinical trials. Many pharmaceutical and biological 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, 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 de-orphanized GPCRs that we develop independently, we are unable to develop related product candidates that successfully complete preclinical or clinical testing. 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 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.

### **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 and the methods used to manufacture them, and related to therapeutic targets and methods of treatment, as well as successfully defending these patents against potential

**Table of Contents**

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 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. 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 and, if our pending PharmacoSurgery patent applications issue as patents, October 20, 2019 for OMS103HP, 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 issue as patents or of the scope of any claims that may issue from these pending and future patent applications, or 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;

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;



## **Table of Contents**

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 OMS103HP, OMS302, OMS201, MASP-2, Addiction, PDE10, PDE7 and GPCR programs, these searches may not have identified all third-party patents relevant to these programs. 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 except for 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.

## **Table of Contents**

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

**Our former chief financial officer has filed a lawsuit against us and our current and former directors, the defense of which 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.**

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. 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 these grant matters.

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. Although we have been advised by outside employment and corporate counsel that we have meritorious defenses to Mr. Klein's allegations, and we intend to defend 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 first-year compliance under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the NASDAQ Stock Market. These rules and regulations have increased our legal and financial compliance costs and made some activities more time-consuming and costly. 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 used to be available. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

We are not currently required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, and are therefore not required to make an assessment of the effectiveness of our internal controls over financial reporting. Further, our independent registered public accounting firm has not been engaged to express, nor has it expressed, an opinion on the effectiveness of our internal controls over financial reporting. We will be required under Section 404 to perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our





## **Table of Contents**

independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting for fiscal years ending after December 31, 2009. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses.

If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, management may not be able to assess whether our internal controls over financial reporting are 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 develop and 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 de-orphanize orphan GPCRs. If any of these companies are able to de-orphanize an 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 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 to adapt, 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

## **Table of Contents**

can involve additional testing and data review. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these Risk Factors. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. The failure to obtain these approvals could harm our business.

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

Our future revenue and profit will depend heavily on the availability of adequate reimbursement for the use of our approved 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 you no assurances at this time regarding their cost-effectiveness and the amount, if any, or method of reimbursement. 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 are 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.**

## **Table of Contents**

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.

### **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 \$5.02 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- results from our clinical trial programs, including our ongoing Phase 3 clinical program for OMS103HP for use in ACL reconstruction surgery, our ongoing Phase 2b clinical trial for OMS302, our ongoing Phase 1/Phase 2 clinical trial for OMS201, and our ongoing Phase 2 clinical trial for our Addiction program;

- 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 debt facility with BlueCrest, pursuant to which we had a notes payable balance of \$10.1 million as of June 30, 2010;

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

## Table of Contents

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.

**We expect that we will seek to raise 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 plan to seek to raise 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 BlueCrest. 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 July 2010, 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 Opportunity Ltd., or Azimuth, over a 24-month period subject to a maximum of 4,297,495 shares of our common stock. If we elect to use the financing arrangement, the sale of

## **Table of Contents**

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 them 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 existing shareholders could cause our stock price to decline.**

Approximately 14.5 million shares of our common stock became available for sale by our shareholders upon the expiration of lock-up agreements in April 2010. If these shareholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. In addition, approximately 4.9 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, more difficult and prevent attempts by our shareholders to replace or remove our current management.**

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

### **Our management has broad discretion over the use of the net proceeds we received from our initial public offering and that we may receive under our committed equity line financing facility, and we and may not use the net proceeds in ways that increase the value of our stock price.**

We have broad discretion over the use of the net proceeds we received from our initial public offering, and that we may receive if we sell shares of common stock to Azimuth, and we could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

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

**Table of Contents**

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 Number</b>	<b>Description</b>
10.1*	Second Amended and Restated Employment Agreement between the registrant and Gregory A. Demopulos, M.D. dated April 7, 2010.
10.2	Exclusive License Agreement between the registrant and Helion Biotech ApS entered into on April 23, 2010.
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.

\* Incorporated by reference from Exhibit 10.1 to the registrant's Current Report on Form 8-K filed on April 12, 2010 (File No. 001-34475).

Confidential treatment has been requested for portions of this exhibit. These portions are omitted from this Quarterly Report on Form 10-Q and have been filed

separately with  
the Securities  
and Exchange  
Commission.



**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**

Date: August 10, 2010

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

**Table of Contents**

**INDEX OF EXHIBITS**

**Exhibit**

**Number**

**Description**

- |       |   |
|-------|---|
| 10.1* | Second Amended and Restated Employment Agreement between the registrant and Gregory A. Demopoulos, M.D. dated April 7, 2010.  |
| 10.2  | Exclusive License Agreement between the registrant and Helion Biotech ApS entered into on April 23, 2010.   |
| 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.  |

\* Incorporated by reference from Exhibit 10.1 to the registrant's Current Report on Form 8-K filed on April 12, 2010 (File No. 001-34475).

Confidential treatment has been requested for portions of this exhibit. These portions are omitted from this Quarterly Report on Form 10-Q and have been filed separately with the Securities and Exchange Commission.