OMEROS CORP
Form 10-Q
November 19, 2009

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009

or

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

For the transition period from _____ to _____

Commission file number: 001-34475

OMEROS CORPORATION

(Exact name of registrant as specified in its charter)

Washington	**91-1663741**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
1420 Fifth Avenue, Suite 2600 Seattle, Washington	**98101**
(Address of principal executive offices)	**(Zip Code)**

(206) 676-5000

(Registrant s telephone number, including area code)

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

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 o No o

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 o	Accelerated filer o	Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of November 16, 2009, the number of outstanding shares of the registrant s common stock, par value $0.01 per share, was 21,272,405.

OMEROS CORPORATION
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2009
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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2009 (unaudited)	December 31, 2008 Note 1
Assets		
Current assets:		
Cash and cash equivalents	$ 1,367	$ 12,726
Short-term investments	3,125	7,256
Grant and other receivables	320	207
Prepaid expenses and other current assets	128	289
Total current assets	4,940	20,478
Deferred offering costs	1,034	
Property and equipment, net	681	918
Intangible assets, net		60
Restricted cash	193	193
Other assets	62	32
Total assets	$ 6,910	$ 21,681
Liabilities, convertible preferred stock and shareholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,530	$ 1,229
Accrued expenses	3,739	3,764
Preferred stock warrant liability	902	1,780
Deferred revenue	1,019	232
Current portion of notes payable	4,750	16,556
Total current liabilities	11,940	23,561
Notes payable, less current portion	9,244	118
Commitments and contingencies		
Convertible preferred stock:		
Issued and outstanding shares 11,514,506 at September 30, 2009 (unaudited) and 11,392,057 at December 31, 2008; Liquidation preference of $93,284 at September 30, 2009 (unaudited) and $92,084 at December 31, 2008	91,019	89,168
Shareholders equity (deficit):		
Preferred stock, par value $0.01 per share:		
Authorized shares 13,425,919 at September 30, 2009 (unaudited) and December 31, 2008		

Designated convertible 13,425,919 at September 30, 2009 (unaudited) and December 31, 2008		
Common stock, par value $0.01 per share:		
Authorized shares 20,410,000 at September 30, 2009 (unaudited) and December 31, 2008;		
Issued and outstanding shares 2,930,167 and 2,951,406 at September 30, 2009 (unaudited) and December 31, 2008, respectively	30	30
Additional paid-in capital	7,408	6,150
Accumulated other comprehensive loss	23	(99)
Deficit accumulated during the development stage	(112,754)	(97,247)
Total shareholders deficit	(105,293)	(91,166)
Total liabilities, convertible preferred stock, and shareholders equity (deficit)	$ 6,910	$ 21,681

See notes to consolidated financial statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from June 16, 1994 (Inception) through September 30,
	2009	2008	2009	2008	2009
Grant revenue	$ 442	$ 501	$ 1,010	$ 989	$ 4,403
Operating expenses:					
Research and development	3,692	4,737	12,291	12,755	74,525
Acquired in-process research and development					10,891
General and administrative	1,277	3,428	4,162	6,327	36,645
Total operating expenses	4,969	8,165	16,453	19,082	122,061
Loss from operations	(4,527)	(7,664)	(15,443)	(18,093)	(117,658)
Investment income	47	114	189	574	5,352
Interest expense	(540)	(52)	(1,705)	(90)	(2,334)
Other income (expense)	1,104	222	1,452	165	1,886
Net loss	$ (3,916)	$ (7,380)	$ (15,507)	$ (17,444)	$ (112,754)
Basic and diluted net loss per common share	$ (1.34)	$ (2.54)	$ (5.29)	$ (6.07)	
Weighted-average shares used to compute basic and diluted net loss per common share	2,930,391	2,909,688	2,929,728	2,871,704	
Pro forma basic and diluted net loss per common share	$ (0.33)	$ (0.52)	$ (1.14)	$ (1.21)	
Weighted-average pro forma shares used to compute pro forma basic and diluted net loss per share	14,444,897	14,301,745	14,422,465	14,263,761	

See notes to consolidated financial statements

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

	Nine Months Ended September 30,		Period from June 16, 1994 (Inception) through September 30,
	2009	2008	2009
Operating activities			
Net loss	$ (15,507)	$ (17,444)	$ (112,754)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	348	317	1,899
Stock-based compensation expense	1,242	1,598	11,400
Change in fair value of preferred stock warrant values and success fee liability	(863)	216	(268)
Non-cash interest expense	191	9	246
Loss on sale of investment securities	30	71	75
Write-off of deferred public offering costs		1,462	1,948
Acquired in-process research and development			10,891
Other than temporary impairment loss on investments			163
Changes in operating assets and liabilities, net of effect from nura acquisition in 2006:			
Grant and other receivables	(113)	(193)	980
Prepaid expenses and other current and noncurrent assets	93	31	(79)
Deferred public offering costs	(1,034)		(2,982)
Accounts payable and accrued expenses	314	(470)	4,972
Deferred revenue	787	(500)	(281)
Net cash used in operating activities	(14,512)	(14,903)	(83,790)
Investing activities			
Purchases of property and equipment	(51)	(144)	(1,844)
Purchases of investments	(3,201)		(87,098)
Proceeds from the sale of investments	6,545	5,572	39,216
Proceeds from the maturities of investments	879	4,550	44,543
Cash paid for acquisition of nura, net of cash acquired of $87			(212)
Net cash provided by (used in) investing activities	4,172	9,978	(5,395)
Financing activities			
Proceeds from borrowings under note payable, net of loan origination costs		4,883	16,928
Payments on notes payable	(2,833)	(1,010)	(5,289)

Proceeds from issuance of common stock and exercise of stock options	11	39	653
Proceeds from the repayment of related party notes receivable			239
Proceeds from issuance of convertible preferred stock, net of issuance costs	1,851		73,034
Issuance of Series E convertible preferred stock for $5.00 per share concurrent with acquisition of nura			5,200
Repurchase of Series A convertible preferred stock and unvested common stock	(48)		(213)
Net cash provided by (used in) financing activities	(1,019)	3,912	90,552
Net (decrease) increase in cash and cash equivalents	(11,359)	(1,013)	1,367
Cash and cash equivalents at beginning of period	12,726	5,925	
Cash and cash equivalents at end of period	$ 1,367	$ 4,912	$ 1,367
Supplemental cash flow information			
Cash paid for interest	$ 1,514	$ 48	$ 2,030
Purchase of equipment included in accounts payable and accrued expenses	$	$ 78	$
Purchase of software financed with note payable	$	$	$ 143
Vesting of early-exercised stock options	$ 5	$	$ 106
Issuance of warrants in connection with notes payable	$	$ 241	$ 253
Issuance of common stock in exchange for note receivable from related party	$	$	$ 239
Preferred stock and common stock issued in connection with nura acquisition	$	$	$ 14,070

See notes to consolidated financial statements

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OMEROS CORPORATION
(A Development Stage Company)
NOTES TO CONOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Note 1 Organization and Significant Accounting Policies

Organization

Omeros Corporation (Omeros or the Company) is a biopharmaceutical company committed to discovering, developing and commercializing products focused on inflammation and disorders of the central nervous system. The Company s most clinically advanced product candidates are derived from its proprietary PharmacoSurgery platform designed to improve clinical outcomes of patients undergoing arthroscopic, ophthalmological, urological and other surgical and medical procedures. As substantially all efforts of the Company have been devoted to conducting research and development of its products, to developing its patent portfolio and to raising equity capital, the Company is 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 (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of September 30, 2009 and for the three and nine months ended September 30, 2009 and 2008, includes all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company s interim financial information. The consolidated balance sheet at December 31, 2008 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 should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2008 included in the Company s Registration Statement on Form S-1 (as amended), which was declared effective by the Securities and Exchange Commission (the SEC) on October 7, 2009.

The consolidated financial statements include the financial position and results of operations of Omeros and nura, inc. (nura), its wholly-owned subsidiary. The acquisition of nura was accounted for as an asset purchase, and the results of nura have been included in the results of the Company since August 11, 2006.

Reverse Stock Split

On August 13, 2009 and September 8, 2009, the Board of Directors and shareholders, respectively, approved a 1-for-1.96 reverse stock split of the Company s convertible preferred stock and common stock. The Company effected the reverse stock split on October 2, 2009. All share and per share amounts have been retroactively restated in the accompanying financial statements and notes for all periods presented. Upon the completion of the Company s initial public offering (IPO) on October 13, 2009, the authorized capital stock of the Company consisted of 150,000,000 shares of common stock and 20,000,000 shares of preferred stock, each with a par value of $0.01 per share.

Initial Public Offering

On October 7, 2009, the Company s Registration Statement on Form S-1/A was declared effective for its IPO, pursuant to which the Company sold 6,820,000 shares of its common stock at a public offering price of $10.00 per share. The Company received gross proceeds of approximately $68.2 million from this transaction, before underwriting discounts and commissions. In connection with the closing of the IPO, all of the Company s shares of preferred stock outstanding at the time of the offering were automatically converted into 11,514,506 shares of common stock, and Series E preferred stock warrants to purchase up to 197,478 shares of Series E convertible preferred stock were converted into common stock warrants to purchase 197,478 shares.

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Liquidity

The Company has incurred significant losses from operations since its inception and expects losses to continue for the foreseeable future. The Company s success depends primarily on the development and regulatory approval of its product candidates. From June 16, 1994 (inception) through September 30, 2009, the Company has incurred cumulative net losses of $112.8 million. Net losses may continue for at least the next several years as the Company proceeds with the development of its product candidates and programs. The size of these losses will depend on receipt of revenue from its products candidates and programs, if any, and on the level of the Company s expenses. To achieve profitable operations, the Company must successfully identify, develop, partner and/or commercialize its product candidates and programs. Product candidates developed by the Company will require approval of the U.S. Food and Drug Administration (FDA) or a foreign regulatory authority prior to commercial sales. The regulatory approval process is expensive, time-consuming and uncertain, and any denial or delay of approval could have a material adverse effect on the Company s ability to become profitable or continue operations. Even if approved, the Company s product candidates may not achieve market acceptance and could face competition.

The Company s cash, cash equivalents and short-term investments decreased from $20.0 million as of December 31, 2008 to $4.5 million as of September 30, 2009. Upon completion of its IPO of 6,820,000 shares of its common stock at a price of $10.00 per share on October 13, 2009, the Company received net proceeds of approximately $61.8 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by the Company following the offering. The Company may seek additional sources of financing through collaborations with third parties or public or private debt or equity financings. If the Company requires additional financing, there can be no assurance that it will be available on satisfactory terms or at all. If adequate funds are not available, the Company may be required to significantly reduce expenses related to its operations and/or delay or reduce the scope of its development programs.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements for the year ended December 31, 2008 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company s ability to continue as a going concern.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Deferred Public Offering Costs

Deferred public offering costs totaled $1.0 million and $0 at September 30, 2009 and December 31, 2008, respectively, and represent primarily legal, accounting and other direct costs related to the Company s efforts to raise capital through the IPO. Deferred public offering costs capitalized prior to 2009 were written-off to expense in 2008. The write-off of previously capitalized costs was based on the guidance provided in SEC Staff Accounting Bulletin (SAB) Topic 5A Deferred Offering Costs. The amount written-off to expense totaled $1.9 million for the year ended December 31, 2008. All costs incurred in 2009 related to the Company s IPO activities were deferred until the completion of the IPO on October 13, 2009, at which time they were reclassified to additional paid-in capital as a reduction of the IPO proceeds.

Intangible Assets

In August 2006, the Company acquired certain intangible assets related to the acquisition of nura. The Company assigned a value of $310,000 to assembled and trained workforce with an amortizable life of three years. The accumulated amortization of the assembled workforce was $310,000 and $250,000 at September 30, 2009 and December 31, 2008, respectively. The intangible assets are fully amortized as of September 30, 2009.

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Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2009	December 31, 2008
	(in thousands)	
Clinical trials	$ 1,754	$ 1,644
Contract preclinical research	100	423
Employee compensation	287	319
Success fee liability related to notes payable	340	310
Public offering costs	640	345
Other accruals	618	723
Accrued expenses	$ 3,739	$ 3,764

See Note 4 for a discussion of the success fee liability.

Preferred Stock Warrant Liability

Warrants to purchase the Company s convertible preferred stock are classified as liabilities and are recorded at fair value. At each reporting period, any change in fair value of the freestanding warrants is recorded as other expense or income.

For the three months ended September 30, 2009 and 2008 and for the nine months ended September 30, 2009 and 2008, the Company recorded (income) expense of $(918,000), $(69,000), $(878,000) and $216,000, respectively, to reflect the change in the estimated fair value of the freestanding preferred stock warrants. The warrant liability was reclassified to equity upon the completion of the Company s IPO in October 2009 with the conversion of the preferred stock warrants to common stock warrants.

Revenue

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 revenue 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.

The Company s revenue since inception relates to grant funding from third parties. The Company recognizes such funds as revenue when the related qualified research and development expenses are incurred up to the limit of the approved funding amounts. Funds received in advance are recorded as deferred revenue and recognized as revenue as research is performed.

The Company has received Small Business Innovative Research (SBIR) grants from the National Institutes of Health since inception totaling $3.2 million and $2.3 million as of September 30, 2009 and December 31, 2008, respectively. The purpose of the grants is to support research for product candidates being developed by the Company. For the three months ended September 30, 2009 and 2008 and for the nine months ended September 30, 2009 and 2008, the Company recorded revenue related to these grants of $192,000, $379,000, $315,000 and $489,000, respectively. As of September 30, 2009, $809,000 of funding remained under these grants.

In December 2006, the Company entered into a funding agreement with The Stanley Medical Research Institute (SMRI) to develop a proprietary PDE10 inhibitor product candidate for the treatment of schizophrenia. The funding is expected to advance the Company s PDE10 program though the completion of Phase 1 clinical trials. Under the agreement, the Company may receive grant and equity funding of up to $9.0 million upon achievement of research milestones. The Company holds the exclusive rights to the technology. In consideration for SMRI s grant funding, the Company 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, the Company is not required to repay the grant funds. As

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of September 30, 2009 and December 31, 2008, the Company has received from SMRI a total of $5.7 million and $2.6 million, respectively. As of September 30, 2009, amounts included in the accompanying balance sheet pertaining to this agreement included $899,000 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. For the three months ended September 30, 2009 and 2008 and for the nine months ended September 30, 2009 and 2008, the Company recognized revenue under this agreement of $119,000, $122,000, $350,000 and $500,000, respectively.

In November 2008, the Company entered into an agreement with The Michael J. Fox Foundation (MJFF) to provide funding for a study of PDE7 inhibitors for the treatment of Parkinson s disease. The agreement is for a one-year period and provides funding of actual costs incurred up to a total of $464,000. In consideration of MJFF s grant funding, MJFF will receive access to the study data results, subject to certain restrictions on data sharing. The Company holds and will continue to hold the exclusive rights to the technology and has no future obligation to MJFF for royalties or other monetary consideration resulting from the ongoing development of the technology. The Company has received total payments from MJFF of $464,000, which consist of an advance payment of $232,000 received in December 2008 and a second advance payment of $232,000 received in July 2009. The payments were initially recorded as deferred revenue. The funds have been recognized as revenue as the related expenses have been incurred. For the three months and nine months ended September 30, 2009, the Company recognized revenue of $131,000 and $344,000, respectively. No revenue was recognized under this agreement prior to 2009. The remaining $120,000 of deferred revenue will be recognized as revenue as research is performed.

Research and Development

Research and development costs are comprised primarily of costs for personnel, including salaries and benefits; occupancy; clinical studies performed by third parties; materials and supplies to support the Company s clinical programs; contracted research; manufacturing; related consulting arrangements; and other expenses incurred to sustain the Company s overall research and development programs. Internal research and development costs are expensed 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. Clinical trial expenses require certain estimates based upon an estimated cost per patient that varies depending on the clinical site and trial.

In-Process Research and Development

In connection with the acquisition of nura in August 2006, the Company recorded an expense of $10.9 million for acquired in-process research and development. This amount represented the estimated fair value related to incomplete product candidate development projects for which, at the time of the acquisition, technological feasibility had not been established and there was no alternative future use.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

Other Comprehensive Loss

Other comprehensive loss is comprised of net loss and certain changes in equity that are excluded from net loss. The Company s only component of other comprehensive loss is unrealized gains (losses) on available-for-sale securities. The components of other comprehensive loss are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(in thousands)			
Net loss	$ (3,916)	$ (7,380)	$ (15,507)	$ (17,444)
Unrealized gain (loss) on available-for-sale securities	(32)	(21)	122	(18)

Other comprehensive loss	$ (3,948)	$ (7,401)	$ (15,385)	$ (17,462)

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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, less weighted-average unvested common shares subject to repurchase. 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.

Net loss attributable to common shareholders for each period must be allocated to common stock and participating securities to the extent that the securities are required to share in the losses. The Company s convertible preferred stock does not have a contractual obligation to share in losses of the Company. As a result, basic net loss per common share is calculated by dividing net loss by the weighted-average shares of common stock outstanding during the period.

The following table presents the computation of basic and diluted net loss per common share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Historical				
Numerator:				
Net loss	$ (3,916)	$ (7,380)	$ (15,507)	$ (17,444)
Denominator:				
Weighted-average common shares outstanding	2,938,965	2,950,824	2,948,653	2,933,278
Less: Weighted-average unvested common shares subject to repurchase	(8,574)	(41,136)	(18,925)	(61,574)
Denominator for basic and diluted net loss per common share	2,930,391	2,909,688	2,929,728	2,871,704
Basic and diluted net loss per common share	$ (1.34)	$ (2.54)	$ (5.29)	$ (6.07)

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

	September 30,	
	2009	2008
Convertible preferred stock	11,514,506	11,391,534
Outstanding options to purchase common stock	2,809,426	2,879,843
Warrants to purchase common stock and convertible preferred stock	234,230	216,417
Common stock subject to repurchase		37,142
Total	14,558,162	14,524,936

The disclosure below shows what basic net loss per share would have been if the conversion of the Company s shares of redeemable convertible preferred stock, that occurred in connection with the IPO that was completed on October 13, 2009, had occurred at the beginning of the respective periods being reported using the as if-converted method. Management believes that this pro forma information provides meaningful supplemental information that helps investors compare the results of prior periods after giving effect to the change in capitalization resulting from the conversion of preferred stock to common stock. The Company s pro forma basic net loss per share is as follows (in thousands, except per share data):

	Three Months Ended	Nine Months Ended

	September 30,		September 30,	
	2009	2008	2009	2008
Pro Forma (unaudited)				
Numerator:				
Net loss	$ (3,916)	$ (7,380)	$ (15,507)	$ (17,444)
Plus: other (income) expense attributable to the convertible preferred stock warrants assumed to have been converted to common stock warrants	(918)	(69)	(878)	216
Pro forma net loss	$ (4,834)	$ (7,449)	$ (16,385)	$ (17,228)

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Denominator:				
Denominator for basic and diluted net loss per common share	2,930,391	2,909,688	2,929,728	2,871,704
Plus: weighted-average pro forma adjustments to reflect assumed conversion of convertible preferred stock	11,514,506	11,392,057	11,492,737	11,392,057
Denominator for pro forma basic and diluted net loss per common share	14,444,897	14,301,745	14,422,465	14,263,761
Pro forma basic and diluted net loss per common share	$ (0.33)	$ (0.52)	$ (1.14)	$ (1.21)

Unaudited pro forma basic and diluted net loss per common share and shares used in computations of pro forma basic and diluted net loss per common share assume conversion of all shares of convertible preferred stock into common stock, conversion of all convertible preferred stock warrants into common stock warrants as of January 1, 2008 or the date of issuance, if later.

Stock-Based Compensation

The Company accounts for stock-based compensation under applicable accounting standards using the prospective method, which requires that the measurement and recognition of compensation expenses for all future share-based payments made to employees and directors be based on estimated fair values. The Company is using the straight-line method to allocate compensation cost to reporting periods over the optionees requisite service period, which is generally the vesting period.

Stock options granted to non-employees are accounted for using the fair value approach and are subject to periodic revaluation over their vesting terms.

For purposes of estimating the fair value of its common stock for stock option grants, the Company reassessed the estimated fair value of its common stock at the end of each quarterly period during the nine months ended September 30, 2009 and the year ended December 31, 2008. For the quarter ended September 30, 2009, the Company used the $10.00 per share offering price from its IPO, which was declared effective by the SEC on October 7, 2009 and completed on October 13, 2009. For other quarters in 2009 and 2008, the Company performed a valuation analysis at the end of each quarter. As a result, certain stock options granted during 2009 and 2008 had an exercise price different than the re-assessed estimated fair value of the common stock at the date of grant. The Company used these fair value estimates derived from its valuations to determine the stock compensation expense, which is recorded in its consolidated financial statements. The valuations were prepared using a methodology that first estimated the fair value of the company as a whole, and then allocated a portion of the enterprise value to common stock.

Segments

The Company operates in only one segment. Management uses cash flow as the primary measure to manage its business and does not segment its business for internal reporting or decision-making.

Adoption of Standards

Effective January 1, 2009, the Emerging Issues Task Force (EITF) issued guidance over accounting for collaborative arrangements. This guidance requires disclosure of the nature and purpose of the Company s significant collaborative arrangements in the annual financial statements, including the Company s rights and obligations under the arrangement, the amount and income statement classification of significant financial expenditures and commitments, and a description of accounting policies for the arrangement. This guidance requires the Company to apply as a change in accounting principle through retrospective application to all prior periods for all applicable

collaborative arrangement existing as of the effective date. There was no impact to the Company s results of operations or financial position upon adoption.

In April 2009, in response to the current credit crisis, the Financial Accounting Standards Board (FASB) issued new guidance to address fair value measurement concerns. This guidance is effective for interim and annual periods ending after June 15, 2009. The adoption of the fair value guidance did not impact the Company s financial condition or results of operations. The new guidance is summarized as follows:

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Additional guidance on measuring the fair value of financial instruments when market activity has decreased and quoted prices may reflect distressed transactions.

Expanded guidance for recognition and presentation of other-than-temporary impairments on debt and equity securities in the financial statements.

Expanded fair value disclosures required for financial instruments to interim reporting periods, including disclosure of the significant assumptions used to estimate the fair value of those financial instruments.

In June 2009, the FASB issued guidance on the accounting for and disclosure of subsequent events. This guidance required application of the requirements to interim or annual financial periods ending after June 15, 2009. The adoption of this guidance did not impact the financial statements of the Company.

Subsequent Events

The Company evaluated events that occurred subsequent to September 30, 2009 through the date of issuance of these financial statements on November 19, 2009. There were no material recognized or non-recognized subsequent events during this period other than events described in this Form 10-Q.

Note 2 Cash, Cash Equivalents and Investments

Cash, cash equivalents, restricted cash and short-term investments, all of which are carried at fair value, consisted of the following:

	September 30, 2009			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
Cash and cash equivalents	$ 1,561	$	$	$ 1,561
Mortgage-backed securities	3,102	24	(1)	3,125
Total	$ 4,663	$ 24	$ (1)	$ 4,686
Amounts classified as cash and cash equivalents				$ 1,367
Amounts classified as restricted cash				193
Amounts classified as short-term investments				3,125
Total				$ 4,685

	December 31, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
Cash and cash equivalents	$ 12,919	$	$	$ 12,919
Mortgage-backed securities	7,355	3	(102)	7,256
Total	$ 20,274	$ 3	$ (102)	$ 20,175

Amounts classified as cash and cash equivalents	$ 12,726
Amounts classified as restricted cash	193
Amounts classified as short-term investments	7,256
Total	$ 20,175

The following table shows the fair value of the Company s investments securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and by whether the securities have been in a continuous unrealized loss position for less than 12 months or for 12 months or greater as of September 30, 2009 and December 31, 2008, respectively.

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	September 30, 2009					
	Less than 12 Months		12 Months or Greater		Total	
Description of Securities	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
	(in thousands)					
Mortgage-backed securities	$ 991	$ (1)	$ 54	$	$ 1,045	$ (1)

	December 31, 2008					
	Less than 12 Months		12 Months or Greater		Total	
Description of Securities	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
	(in thousands)					
Mortgage-backed securities	$ 4,512	$ (59)	$ 2,123	$ (43)	$ 6,635	$ (102)

The Company owned three and nine securities with unrealized loss positions as of September 30, 2009 and December 31, 2008, respectively. The Company believes that the unrealized losses in the table above are not other-than-temporary. The unrealized losses are driven primarily by market illiquidity that has caused price deterioration. The Company assesses the fundamentals of these securities to identify their individual sources of risk and potential for other-than-temporary impairment. The assessment includes 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, 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 Company s investment portfolio is made up of cash, cash equivalents, and mortgage-backed, adjustable-rate securities issued by, or fully collateralized by, the U.S. government or U.S. government-sponsored entities. The mortgage-backed securities have contractual maturities ranging from six to 29 years at September 30, 2009, and ranging from seven to 31 years at December 31, 2008. Due to normal annual prepayments, the estimated average life of the portfolio is approximately three to five years. The adjustable rate feature, which is not dependent on an auction process, further shortens the duration and interest risk of the portfolio, making it similar to a one-year government agency security. All investments are classified as short-term and available-for-sale on the accompanying balance sheets.

To determine the fair market value of its mortgage-backed securities, the Company s external investment manager formally prices securities at least monthly with external market sources. The external sources have historically been primary and secondary broker/dealers that trade and make markets in an open market exchange of these securities. Mortgage-backed securities are priced using round lot non-binding pricing from a single external market source for each of the investment classes within the Company s portfolio. The Company has used this non-binding pricing information to estimate fair market value and does not make adjustments to these quotes unless a review indicates an adjustment is warranted. To determine pricing, the external market sources use inputs other than quoted prices in active markets that are either directly or indirectly observable such as trading activity that is observable in these securities or similar or like-kind securities, rate reset margins, reset indices, pool diversification and prepayment levels. In addition, in evaluating if this pricing information should be adjusted, the prices obtained from these external market sources are compared against independent pricing services.

The composition of the Company s investment income is as follows:

	Nine Months Ended

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(in thousands)			
Gross interest income	$ 70	$ 130	$ 220	$ 645
Gross realized gains on investments	7	5	7	14
Gross realized losses on investments	(29)	(21)	(38)	(85)
Total investment income	$ 48	$ 114	$ 189	$ 574

Realized gains and losses on sales of investments are calculated based on the specific identification method.

Note 3 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

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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 established 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:

These levels include:

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 the Company, which reflect those that a market participant would use.

As of September 30, 2009 and December 31, 2008, no assets or liabilities are measured at fair value on a nonrecurring basis. The Company s fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis are as follows:

	September 30, 2009			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets:				
Money market funds	$ 1,357	$	$	$ 1,357
Mortgage-backed securities		3,125		3,125
Total	$ 1,357	$ 3,125	$	$ 4,482
Liabilities:				
Preferred stock warrant liability	$	$	$ 902	$ 902
Notes payable success fee liability			340	340
Total	$	$	$ 1,242	$ 1,242

	December 31, 2008			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets:				
Money market funds	$ 12,783	$	$	$ 12,783
Mortgage-backed securities		7,256		7,256
Total	$ 12,783	$ 7,256	$	$ 20,039
Liabilities:				
Preferred stock warrant liability	$	$	$ 1,780	$ 1,780
Notes payable success fee liability			310	310
Total	$	$	$ 2,090	$ 2,090

The change in fair value of the Company s short-term investments are included in accumulated other comprehensive income (loss) in the accompanying balance sheets. The change in fair value of the Company s preferred stock warrant liability and notes payable success fee liability are recorded as other income (expense) in the

consolidated statements of operations. For the nine months ended September 30, 2009 and the year ended December 31, 2008, the change in fair value of the preferred stock warrant liability and notes payable success fee liability are as follows:

	Preferred Stock Warrant Liability	Notes Payable Success Fee Liability
	(in thousands)	
Fair value at December 31, 2008	$ 1,780	$ 310
Change in fair value	(878)	30
Fair value at September 30, 2009	$ 902	$ 340

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See Note 6 for a discussion of the valuation methodology used to estimate the fair value of the preferred stock warrant liability. See Note 4 for a discussion of the valuation methodology used to estimate the fair value of the notes payable success fee liability.

Note 4 Notes Payable

Loan and Security Agreement

In September 2008, the Company entered into a loan and security agreement with BlueCrest Capital Finance, L.P. (BlueCrest) to borrow up to $20.0 million in four tranches. The Company has borrowed a total of $17.0 million under the agreement. Interest on borrowings under the loan agreement is at an annual rate of 12.5%. Repayments of advances under the loan are made monthly, on the first of the month following the date of each applicable advance. Payments are interest only for the first three months and interest and principal thereafter for 36 months. Under the loan agreement, the Company 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 borrowings then currently outstanding.

Material adverse effect (MAE) is defined in the loan agreement as a material adverse effect upon (i) the business operations, properties, assets, results of operations or financial condition of the Company, taken as a whole with respect to the Company s viability, that reasonably would be expected to result in the Company s inability to repay any portion of the loans in accordance with the terms of the loan agreement, (ii) the validity, perfection, value or priority of BlueCrest s security interest in the collateral, (iii) the enforceability of any material provision of the loan agreement or related agreements or (iv) the ability of BlueCrest to enforce its rights and remedies under the loan agreement or related agreements. The Company considered the MAE definition in the agreement as subjective and classified all of the outstanding notes payable as current liabilities in the consolidated balance sheet as of December 31, 2008 based on the uncertainty as to whether BlueCrest would utilize the material adverse effect clause and call a portion or all of the notes payable to them. However, due to the improved liquidity following the completion of the Company s IPO, the Company believes that it is less likely that the MAE clause would be triggered, and accordingly, the portion of the note payable that is due in more than one year has been reclassified to long-term liabilities as of September 30, 2009.

The proceeds of the loan may be used for working capital, capital expenditures and general corporate purposes, and the loan is collateralized by substantially all of the Company s assets, other than intellectual property. The Company 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 draw. If a prepayment is made more than 18 months after the date of the applicable draw, then the prepayment premium is reduced to 1.0%.

As a condition to BlueCrest making the initial $5.0 million loan, the Company agreed to pay a fee (Success Fee) to BlueCrest in an amount up to $400,000 should certain exit events (as defined) occur prior to September 12, 2018. The Success Fee was pro rated based on the ratio of the actual amounts borrowed under the loan agreement to the total $20.0 million that could be borrowed. An exit event is defined in the agreement as including, among other things, a change in control of the Company, a sale of all or substantially all of the Company s assets, or an initial public offering of the Company s common stock. The Success Fee was determined to be an embedded derivative which is recorded at estimated fair value in the accompanying financial statements. The potential future obligation of the pro rated Success Fee was $340,000 at September 30, 2009 and December 31, 2008, based on the $17.0 million borrowed to date under the loan agreement. The fair value of the pro rated Success Fee was estimated at the time of borrowing based on the estimated probability and date of occurrence of the exit events, discounted to present value using the Company s estimated cost of capital. The fair value of the fee was recorded as a success fee liability with an offsetting reduction in notes payable accounted for as a debt discount. The debt discount is being amortized to interest expense using the effective interest method over the repayment term of the initial loan amount. The success fee liability was adjusted to fair value on a recurring basis, with changes in fair value recorded as other income (expense) in the consolidated statements of operations. At September 30, 2009 and December 31, 2008, the estimated fair value of the pro rated success fee liability was $340,000 and $310,000, respectively, and is included in accrued expenses in the consolidated balance sheet. In

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October 2009, following the completion of the IPO, the Company paid BlueCrest $340,000 for the Success Fee. The Company has no further obligation to pay a success fee to BlueCrest.

In connection with the execution of and subsequent draws under the loan and security agreement, the Company issued two warrants to BlueCrest to purchase common stock at an exercise price of $13.48 per share. The warrants vested in tranches as amounts are borrowed under the loan agreement. As of September 30, 2009 and December 31, 2008, a total of 25,213 common stock warrants had vested under the first warrant in connection with the drawdowns of the first three tranches available under the loan agreement. The fair value of the vested warrant was $241,000, determined using the Black-Scholes option-pricing model, and was recorded as additional paid-in capital and as a discount to the note. The debt discount is being amortized to interest expense using the effective interest method over the repayment term of the initial loan amount. Non-cash interest expense associated with amortization of the debt discount totaled $54,000, $7,000, $153,000 and $7,000 for the three months ended September 30, 2009 and 2008 and for the nine months ended September 30, 2009 and 2008, respectively. The first warrant was fully vested as of September 30, 2009 and, because the Company did not borrow the fourth tranche, no shares will vest under the second warrant. The fair value of the second warrant was determined to be $0 based on the probability that the funds available for borrowing under the fourth tranche of the loan agreement would not be drawn. These warrants terminated, without being exercised, on October 13, 2009 upon completion of the Company s IPO.

In connection with the loan and security agreement, the Company incurred debt issuance costs of $122,000 that were capitalized and included in other assets in the December 31, 2008 balance sheet. The debt issuance costs are being amortized to interest expense using the effective interest method over the repayment term of the initial loan amount. Non-cash interest expense associated with amortization of the debt issuance costs totaled $12,000, $2,000, $38,000, and $2,000 for the three months ended September 30, 2009 and 2008 and for the nine months ended September 30, 2009 and 2008, respectively. The remaining unamortized balance is $71,000 at September 30, 2009 and is included in other assets in the balance sheet.

The unamortized debt discount is $366,000 and $519,000 at September 30, 2009 and December 31, 2008, respectively.

Note 5 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, the Company may become obligated to pay royalties based on net income, as defined in the agreement, not to exceed a set multiple of total grant funding received. Based on the amount of grant funding received as of September 30, 2009, the maximum amount of royalties payable by the Company is $12.8 million. The Company has not paid any such royalties through September 30, 2009.

The Company previously utilized two contract research organizations for assistance in synthesizing compounds for its PDE10 program, ComGenex, Inc. (ComGenex) and Scottish Biomedical Research, Inc. (Scottish Biomedical). If a clinical product candidate for the PDE10 program is selected that is a compound synthesized by one of these contract research organizations, the Company may be required to make milestone payments to that organization upon the occurrence of certain development events, such as the filing of an investigational new drug application (IND), the initiation of clinical trials, or the receipt of marketing approval. The total milestone payments potentially payable to ComGenex are up to $3.4 million and to Scottish Biomedical are up to $178,000 per compound. In such a case, the Company would also be required to pay a low single-digit percentage royalty to the applicable organization with respect to any sales of a PDE10 inhibitor product that includes the organization s compound. The Company is no longer using either of these contract research organizations to synthesize or develop compounds and the terms of the agreements have ended, although the Company s royalty and milestone payment obligations continue.

In July 2008, the Company entered into a discovery and development agreement with Affitech AS (Affitech) to isolate and optimize fully human antibodies for the Company s mannan-associated serine protease-2 (MASP-2) program. Under the terms of the agreement, Affitech will apply its human antibody libraries and proprietary antibody discovery and screening technologies to generate fully human MASP-2 antibodies for the Company. The Company recorded research and development expense under the agreement totaling $400,000 in 2008. The Company may be required to make additional payments to Affitech of up to $10.1 million upon the achievement of certain development events, such as the

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filing of an IND, initiation of clinical trials, and the receipt of marketing approval for a drug product containing an antibody developed by Affitech. The agreement also stipulates certain optional services that may be requested by the Company for a fee. In addition, the Company is obligated to pay Affitech a low single-digit percentage royalty on any net sales by the Company of drug products containing an antibody developed by Affitech under the agreement. The agreement may be terminated for cause by either party, or at any time by the Company by providing 30 day advance written notice to Affitech.

In September 2008, the Company entered into a technology option agreement with Patobios Limited (Patobios) to evaluate and potentially acquire the intellectual property rights covering Patobios G protein-coupled receptor (GPCR) technology. Under the terms of the agreement, as amended in November 2009, Patobios granted the Company an option to evaluate the technology over four option periods commencing September 2008 and continuing up to December 2010. The Company made a non-refundable payment of $200,000 CAD ($188,000 USD) to Patobios following execution of the agreement for the first nine-month option period and a payment of $522,000 CAD ($471,000 USD) for the second six-month option period, all of which was charged to research and development expense. Unless the agreement is terminated prior to December 2009, the second option period shall be automatically extended until January 2010 at a cost to the Company of $108,333 CAD. If the Company successfully de-orphanizes at least one orphan GPCR, thereby achieving a de-orphanization milestone, and has not purchased the technology by January 2010, the Company will be required to extend the option period from January 2010 to June 2010 at a cost of $541,667 CAD. The Company may also extend the option period for one additional six-month period ending December 2010 at a cost of $500,000 CAD. Under the terms of the agreement, the Company has 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 the Company achieves the de-orphanization milestone, it 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, the Company 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 $5.135 million CAD: (a) the amount paid by the Company to Patobios from licenses granted by the Company 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 the Company specifically allocated for the purchase of the GPCR technology and (c) the $500,000 CAD de-orphanization milestone payment. The agreement may be terminated for cause by either party, at any time by mutual consent of the Company and Patobios, or by the Company at any time prior to the achievement of the de-orphanization milestone.

In October 2008, the Company entered into an antibody development agreement with North Coast Biologics LLC (North Coast) to isolate and optimize antibodies for the Company s 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 the Company. The Company recorded research and development expenses under the agreement totaling $150,000 in 2008. Under the agreement, the Company 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. The agreement also provides an option to the Company to have North Coast generate antibodies for additional targets. If this option is exercised, the Company 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, the Company is obligated to pay North Coast a low single-digit percentage royalty on any net sales by the Company 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, the Company entered into a patent assignment agreement with an individual whereby the Company 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, the Company 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, the

Company is 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.

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Note 6 Warrants

On August 24, 2009, in connection with the planned IPO, the Company waived a termination clause included in certain outstanding warrants to purchase up to 197,478 shares of Series E convertible preferred stock at an exercise price of $12.25 per share that would have caused these warrants to terminate upon completion of the IPO if not previously exercised. The warrants were originally issued in 2007 as compensation for assistance with the Company s Series E convertible preferred stock financing. The holders of these warrants include members of the IPO selling group and related persons, among other persons. As a result of this waiver, the warrants remain outstanding following completion of the IPO and will terminate upon the earlier of (a) a change of control as defined in the warrants and (b) March 29, 2012.

The fair value of the preferred stock warrants is adjusted to fair value at the end of each reporting period using the Black-Scholes option pricing model, based on the following assumptions:

	September 30, 2009	December 31, 2008
Risk-free interest rate	1.20 - 2.72%	2.3%
Weighted-average expected life (in years)	2.5 - 5.00	3.25 - 5.00
Expected dividend yield		
Expected volatility rate	78%	60%

The increase (decrease) in the fair value of the warrants totaled $(918,000), $(69,000), $(878,000), and $216,000 during the three months ended September 30, 2009 and 2008 and during the nine months ended September 30, 2009 and 2008, respectively. These changes in the preferred stock warrant liability are included in other income (expense) in the consolidated statement of operations.

The preferred stock warrant liability was reclassified to additional paid-in-capital upon conversion of the preferred stock warrants to common stock warrants in connection with the IPO that was completed on October 13, 2009.

Note 7 Convertible Preferred Stock

On February 18, 2009, the Company received $3.1 million in connection with the funding agreement with SMRI. Under the terms of the agreement with SMRI, entered into in December 2006, $1.9 million of the funding is characterized as grant funding and the remaining $1.2 million is characterized as equity funding for the purchase of 122,449 shares of the Company s Series E convertible preferred stock at a price of $9.80 per share. At the time of issuance of the Series E convertible preferred stock to SMRI in February 2009, the estimated fair value of the 122,449 shares was $1.9 million, or $15.11 per share, rather than the $1.2 million characterized as equity funding under the agreement. Accordingly, the Company recorded $1.9 million to equity for the 122,449 shares issued to SMRI and the remaining $1.2 million of the proceeds from SMRI as deferred revenue.

Note 8 Stock-Based Compensation

Stock Options

In February 2008, the Company s board of directors adopted the 2008 Equity Incentive Plan (the 2008 Plan) which was subsequently approved by the Company s shareholders in March 2008. 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 the Company s Amended and Restated 1998 Stock Option Plan (the 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 September 30, 2009 and December 31, 2008, an additional 317,531 and 153,479 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 the Company s common stock on the last day of the immediately preceding fiscal year;

1,785,714 shares; or

such other amount as the Company s board of directors may determine.

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A summary of stock option activity and related information follows:

	Shares Available for Grant	Options Outstanding	Weighted-Average Exercise Price per Share
Balance at December 31, 2008	1,020,728	2,839,850	$ 1.40
Authorized increase in 2008 Plan shares (unaudited)	164,049		
Expired (unaudited)	(164,157)		
Repurchased (unaudited)	25,968		
Granted (unaudited)	(112,496)	112,496	12.41
Exercised (unaudited)		(4,731)	2.33
Cancelled (unaudited)	138,189	(138,189)	1.72
Balance at September 30, 2009 (unaudited)	1,072,281	2,809,426	$ 1.82

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 nine months ended September 30, 2009 was $8.83.

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Expected volatility	78%	60%	71% - 78%	60%
Expected term (in years)	6.08	6.08	6.08	6.08
Risk-free interest rate	2.72%	3.29%	2.13% - 2.72%	2.8% - 3.40%
Expected dividend yield	0%	0%	0%	0%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(in thousands)			
Research and development	$ 91	$ 146	$ 528	$ 631
General and administrative	212	286	714	967
Total	$ 303	$ 432	$ 1,242	$ 1,598

In connection with the non-employee options, the Company recognized expense of $(60,000), $63,000, $94,000, and $198,000 for the three months ended September 30, 2009 and 2008 and for the nine months ended September 30, 2009 and 2008, respectively.

The Company accounts for cash received in consideration for the purchase of unvested shares of common stock or the early-exercise of unvested stock options as a current liability, which is included as a component of accrued liabilities on the Company s balance sheet. As of September 30, 2009 and December 31, 2008 there were zero and 28,762 unvested shares of the Company s common stock outstanding, respectively, and $0 and $54,000 of related recorded liability, respectively, which is included in accrued liabilities.

In February 2009, the Company repurchased 2,584 shares of unvested stock for their original exercise price of $0.98 per share. In August 2009, the Company repurchased an additional 23,384 shares of unvested stock for their original exercise price of $1.96 per share. All of these unvested shares had been issued in connection with the early exercise of stock options. In accordance with the provisions of the 2008 Plan, the repurchased shares increased the authorized shares available under the 2008 Plan.

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Note 9 Related-Party Transactions

The Company conducts research using the services of one of its founders, Pamela Pierce Palmer, M.D., Ph.D. In 2007, the Company granted Dr. Palmer an option to purchase 20,408 shares of common stock and recognized $(29,000), $15,000, $10,000 and $50,000 of non-cash compensation associated with this option for the three months ended September 30, 2009 and 2008 and for the nine months ended September 30, 2009 and 2008, respectively.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, 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:

assuming that we receive positive results from our ongoing Phase 3 clinical trials of OMS103HP in patients undergoing ACL reconstruction surgery, our ability to submit a related NDA to the FDA during the second half of 2010;

our ability to review the data from our first Phase 2 trial of OMS103HP in patients undergoing arthroscopic meniscectomy surgery in the second half of 2009;

our ability to market OMS103HP by 2011, at the earliest;

our expectations regarding the clinical benefits of our PharmacoSurgery product candidate, including whether OMS103HP will be the first commercially available drug product for the improvement of function following arthroscopic surgery;

the magnitude of any royalty obligations that we may become obligated to pay to our service providers or others;

the extent of protection that our patents provide and our pending patent applications may provide, if patents issue from such applications, to our technologies and programs;

our estimate regarding how long our existing cash, cash equivalents and short-term investments, along with the net proceeds from our IPO, will be sufficient to fund our anticipated operating expenses and capital expenditures and the factors impacting our future capital expenditures;

our ability to obtain commercial supplies of our PharmacoSurgery product candidates and our competition;

our ability to enter into a new employment agreement with our chief executive officer;

our ability to meet our repayment and other obligations under our debt facility with BlueCrest, pursuant to which we have borrowed $17.0 million; and

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our estimates regarding our future net losses, revenues and research and development expenses.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in 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 four ongoing PharmacoSurgery clinical development programs, the most advanced of which is in Phase 3 clinical trials. In addition to our PharmacoSurgery platform, we have leveraged our expertise in inflammation and the central nervous system, or CNS, to build a deep and diverse pipeline of preclinical programs targeting large markets. 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, expected to include a total of approximately 1,040 patients, 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 evaluating OMS103HP s safety and ability to reduce pain and improve postoperative joint function following arthroscopic meniscectomy surgery. Assuming that we receive positive results from our ongoing Phase 3 clinical program for ACL reconstruction surgery, we intend to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, under the Section 505(b)(2) NDA process during the second half of 2010. We believe that OMS103HP will, if approved, be the first commercially available drug product for the improvement of function following arthroscopic surgery. In the second half of 2009, we expect to review the data from our first Phase 2 clinical trial in patients undergoing meniscectomy surgery. This is an exploratory study performed to provide a basis on which to design future studies, should we elect to conduct them.

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 recently completed a Phase 1/Phase 2 clinical trial that evaluated the efficacy and safety of OMS302 added to standard irrigation solution and delivered to patients undergoing cataract surgery, and we have completed enrollment in a Phase 2 concentration-ranging clinical trial of the mydriatic active pharmaceutical ingredient, or API, contained in OMS302. A Phase 1/Phase 2 clinical trial of OMS201 is underway in patients undergoing ureteroscopic removal of ureteral or renal stones. We own and exclusively control a U.S.

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and international portfolio of issued patents and pending patent applications that we believe protects our PharmacoSurgery platform.

In addition to our PharmacoSurgery platform, we have a deep and diverse pipeline of preclinical product development programs targeting large market opportunities in inflammation and the CNS covered by a broad intellectual property portfolio. 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. Our CNS pipeline includes our Addiction program, our Phosphodiesterase 10, or PDE10, program, our PDE7 program and our G protein-coupled receptors, or GPCR, program. In our Addiction program, we are developing proprietary compositions that include peroxisome proliferator-activated receptor 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. In our PDE10 program, we are developing proprietary compounds to treat schizophrenia. 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.

We have incurred significant losses since our inception. As of September 30, 2009, our accumulated deficit was $112.8 million and total shareholders deficit was $105.3 million. We recognized net losses of $3.9 million, $7.4 million, $15.5 million and $17.4 million for the three months ended September 30, 2009 and 2008, and for the nine months ended September 30, 2009 and 2008, respectively. These losses have resulted principally from expenses incurred in connection with research and development activities, consisting primarily of clinical trials, preclinical studies, and manufacturing services associated with our current product candidates. We expect our net losses 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.

On October 13, 2009, we completed our initial public offering of 6,820,000 shares of our common stock at a price of $10.00 per share. Net cash proceeds from the public offering were approximately $61.8 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by us following the offering.

Revenue

We have recognized $4.4 million of revenue from inception through September 30, 2009, 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;

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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.

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. In addition, we believe that allocating costs on the basis of time incurred by our employees does not reflect the actual costs of a project.

Research and development expenses since inception to September 30, 2009 were $74.5 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(in thousands)			
Clinical Research and Development				
Salaries, benefits and related costs	$ 873	$ 886	$ 2,784	$ 2,682
Clinical Trials	589	839	1,751	2,423
Manufacturing services, consulting, laboratory supplies, and other costs	510	549	1,222	1,469
Other costs	249	274	826	460
Stock-based compensation	53	88	306	379
Total Clinical Research and Development Expenses	2,274	2,636	6,889	7,713
Preclinical Research and Development				
Salaries, benefits and related costs	602	658	1,933	1,894
Research and preclinical studies, consulting, laboratory supplies, and other costs	423	1,039	2,134	1,907
Other costs	354	346	1,113	989
Stock-based compensation	39	58	222	252
Total Preclinical Research and Development Expenses	1,418	2,101	5,402	5,042
Total Research and Development Expenses	$ 3,692	$ 4,737	$ 12,291	$ 12,755

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

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

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 2011, 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.

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

The preparation of financial statements in conformity with U.S. generally accepted accounting principles, or GAAP, requires us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Some of our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. The following accounting policies involve critical accounting estimates because they are particularly dependent on estimates and assumptions made by management about matters that are highly uncertain at the time the accounting estimates are made. In addition, while we have used our best estimates based on facts and circumstances available to us at the time, different estimates reasonably could have been used. Changes in the accounting estimates we use are reasonably likely to occur from time to time, which may have a material impact on the presentation of our financial condition and results of operations.

Our most critical accounting estimates include revenue recognition; our recognition of research and development expenses, which impacts operating expenses and accrued liabilities; stock-based compensation, which impacts operating expenses; preferred stock warrant liability, which impacts other income (expense) and current liabilities; the fair value measurement of financial instruments; and the classification between short- and long-term liabilities of our notes payable. We review our estimates, judgments and assumptions periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that these estimates are reasonable; however, actual results could differ from these estimates.

In the consolidated balance sheet as of September 30, 2009, $9.2 million of the $14.0 million balance of notes payable has been classified as long-term liabilities because we completed our nitial public offering on October 13, 2009. Previously, the entire balance of notes payable to one of our lenders was classified as a current liability in the consolidated balance sheets

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due to a subjective acceleration clause in the related loan agreement and our inability to repay the notes payable upon demand if that clause was triggered.

Results of Operations

Comparison of Three Months Ended September 30, 2009 and September 30, 2008

Revenue. Revenue was $442,000 for the three months ended September 30, 2009 compared with $501,000 for the three months ended September 30, 2008. The decrease was primarily due to completion of a research project that was funded by National Institutes of Health, or the NIH, and was partially offset by the recognition of additional revenue in connection with other grants awarded to Omeros by the NIH and The Michael J. Fox Foundation, or the MJFF.

Research and Development Expenses. Research and development expenses were $3.7 million for the three months ended September 30, 2009 compared with $4.7 million for the three months ended September 30, 2008. The $1.0 million quarter-over-quarter decrease was due primarily to lower contract service costs associated with several of our clinical and preclinical programs. A lesser portion of the quarter-over-quarter decrease was largely the result of lower clinical trial expenses in the 2009 period due to the prior completion of enrollment in our Phase 2 meniscectomy study evaluating OMS103HP.

General and Administrative Expenses. General and administrative expenses were $1.3 million for the three months ended September 30, 2009 compared with $3.4 million for the three months ended September 30, 2008. The decrease was primarily due to the write-off of $1.9 million of deferred offering costs related to a delay in our initial public offering during the 2008 period.

Investment Income. Investment income was $47,000 for the three months ended September 30, 2009 compared with $114,000 for the three months ended September 30, 2008. The decrease was due primarily to a lower average investment balance and lower market rates.

Interest Expense. Interest expense was $540,000 for the three months ended September 30, 2009 compared with $52,000 for the three months ended September 30, 2008. In September and December of 2008, we had borrowed an aggregate total of $17.0 million with an annual interest rate of 12.5% under a loan and security agreement with BlueCrest Venture Finance Master Fund Limited, assignee of BlueCrest Capital Finance, L.P., or BlueCrest. Interest expense increased in 2009 due to this loan. The interest expense in 2008 was the result of interest incurred on a note that we assumed as a part of our acquisition of nura in 2006. This loan was paid off in September 2008.

Other Income (Expense). Other income was $1.1 million for the three months ended September 30, 2009 compared with $222,000 for the three months ended September 30, 2008. This was primarily due to non-cash income from the decrease in the fair value of warrants in 2009 compared to that in 2008 as well as the addition of sublease tenants subsequent to the 2008 period.

Comparison of Nine Months Ended September 30, 2009 and September 30, 2008

Revenue. Revenue was $1.0 million for the nine months ended September 30, 2009 compared with $989,000 for the nine months ended September 30, 2008. The increase was primarily due to higher grant revenue recognized under our grant from the MJFF, and was partially offset by the recognition of decreased revenue in connection with other grants awarded to Omeros by the NIH and The Stanley Medical Research Institute, or SMRI.

Research and Development Expenses. Research and development expenses were $12.3 million for the nine months ended September 30, 2009 compared with $12.8 million for the nine months ended September 30, 2008. The $500,000 decrease was primarily the result of lower clinical trial expenses in the 2009 period due to the completion of enrollment in our Phase 2 meniscectomy study evaluating OMS103HP during that period as well as lower contract service costs in connection with (1) the completion of manufacturing, validation and stability studies for our clinical programs and (2) one of our preclinical

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programs. The decrease was partially offset by an option period payment of $471,000 that we made to Patobios Limited in connection with our GPCR program.

General and Administrative Expenses. General and administrative expenses were $4.2 million for the nine months ended September 30, 2009 compared with $6.3 million for the nine months ended September 30, 2008. The $2.1 million decrease was due primarily to the write-off of deferred offering costs in 2008 related to our initial public offering as well as a decrease in stock-based compensation from 2008.

Investment Income. Investment income was $189,000 for the nine months ended September 30, 2009 compared with $574,000 for the nine months ended September 30, 2008. The decrease was due primarily to a lower average investment balance and lower market rates.

Interest Expense. Interest expense was $1.7 million for the nine months ended September 30, 2009 compared with $90,000 for the nine months ended September 30, 2008. In September and December of 2008, we had borrowed an aggregate total of $17.0 million with an annual interest rate of 12.5% under a loan and security agreement with BlueCrest. Interest expense increased in 2009 due to this loan. The interest expense in 2008 was the result of interest incurred on a note that we assumed as a part of our acquisition of nura in 2006. This loan was paid off in September 2008.

Other Income (Expense). Other income was $1.5 million for the nine months ended September 30, 2009 compared with $165,000 for the nine months ended September 30, 2008. This was primarily due to non-cash income from the decrease in the fair value of warrants in 2009 compared to that in 2008 as well as the addition of sublease tenants subsequent to the 2008 period.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through private placements of equity securities and, in 2008, through a debt facility. Through September 30, 2009, we received net proceeds of $77.6 million from the sale of shares of our convertible preferred stock. The proceeds have been used to fund our losses.

As of September 30, 2009, we had $4.5 million in cash, cash equivalents and short-term investments. On October 13, 2009, we completed our initial public offering of 6,820,000 shares of our common stock at a price of $10.00 per share. Net cash proceeds from the public offering were approximately $61.8 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by us following the offering. Our cash, cash equivalents and short-term investment balances are held in a variety of interest-bearing instruments, including mortgage-backed securities issued by or fully collateralized by U.S. government or U.S. government-sponsored entities, high-credit-rating corporate borrowers and 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 $14.5 million for the nine months ended September 30, 2009 was primarily due to the net loss for the period of $15.5 million, $1.0 million of deferred offering costs, and $863,000 from the remeasurement of preferred stock warrant and success fee liabilities offset in part by $1.2 million of non-cash stock-based compensation. Net cash used in operating activities of $14.9 million for the nine months ended September 30, 2008 was primarily due to the net loss of $17.4 million, offset in part by $1.6 million of non-cash stock-based compensation expense and $1.5 million from the write-off of deferred offering costs.

Investing activities. Net cash provided by investing activities was $4.2 million for the nine months ended September 30, 2009 primarily due to the proceeds from the sale of investments during the period. Net cash provided by investing activities was $10.0 million for the nine months ended September 30, 2008 primarily due to the sale and maturities of investments in the amount of $10.1 million.

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Financing activities. Net cash used in financing activities was $1.0 million for the nine months ended September 30, 2009 primarily due to principal payments of $2.8 million to BlueCrest on our notes payable, offset by the sale of 122,449 shares of our convertible preferred stock to SMRI with an estimated fair value of $1.9 million. Net cash provided by financing activities was $3.9 million for the nine months ended September 30, 2008, primarily due to borrowing $4.9 million under the loan with BlueCrest, offset by $1.0 million of principal payments to pay off the note we assumed in connection with our acquisition of nura.

In September 2008, we entered into a loan and security agreement with BlueCrest and have borrowed a total of $17.0 million under this agreement in three separate tranches. We cannot borrow any additional amounts under this agreement. As of September 30, 2009, there was $14.2 million of principal outstanding. 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 may use 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 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 was outstanding as of September 30, 2009, but expired upon the closing of our initial public offering in October 2009 without being exercised.

We have 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 I clinical trials totaling $9.0 million, subject to our mutual agreement with SMRI. As of September 30, 2009, we had received $5.7 million from SMRI, $2.5 million of which is characterized as grant funding and $3.2 million of which is characterized as equity funding under the funding agreement.

In November 2008, we entered into an 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 one-year period and provides funding of actual costs incurred up to a total of $464,000. We received an advance payment of $232,000 in December 2008 and a final installment of $232,000 was received in July 2009.

Funding Requirements

We believe that our existing cash, cash equivalents and short-term investments, along with the net proceeds of our IPO, will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 24 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

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amounts of increased capital requirements and operating expenditures required in the future. Our future capital requirements will depend on many factors, including:

- the progress and results of our clinical trials for OMS103HP, OMS302 and OMS201;
- 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 Affitech AS 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; and
- our degree of success in commercializing OMS103HP and other product candidates.

We do not anticipate generating revenue from the sale of our product candidates until 2011 at the earliest. In the absence of additional funding, 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. 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.

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Contractual Obligations and Commitments

There have been no significant changes during the nine months ended September 30, 2009 to the items that we disclosed as our contractual obligations and commitments in our Registration Statement on Form S-1, as amended, for the year ended December 31, 2008.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is primarily confined to our investment securities and notes payable. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality. As of September 30, 2009, we had cash, cash equivalents and short-term investments of $4.5 million. On October 13, 2009, we completed our initial public offering of 6,820,000 shares of our common stock at a price of $10.00 per share. Net cash proceeds from the public offering were approximately $61.8 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by us following the offering. 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. While our investment portfolio includes mortgage-backed securities, we do not hold sub-prime mortgages. Our investments in mortgage-backed securities are issued by, or fully collateralized by, the U.S. government or U.S. government-sponsored entities.

We are exposed to potential loss due to changes in interest rates. Our principal interest rate exposure is to changes in U.S. interest rates related to our investment securities. To estimate the potential loss due to changes in interest rates, we performed a sensitivity analysis using the instantaneous adverse change in interest rates of 100 basis points across the yield curve. On this basis, we estimate the potential loss in fair value that would result from a hypothetical 1% (100 basis points) increase in interest rates to be approximately $14,000 as of September 30, 2009.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive and financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2009. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2009, our chief executive officer and chief 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.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On September 29, 2008 we filed a complaint, now pending in U.S. District Court for the Western District of Washington, against Scottish Biomedical, Ltd., a United Kingdom private limited company, related to contract laboratory services provided by Scottish Biomedical for our PDE10 and PDE7 programs. In our complaint, we allege that Scottish Biomedical breached our contract laboratory services agreement, committed fraud and misrepresentations and fraudulent concealment and violated the Washington Consumer Protection Act. Our complaint seeks unspecified damages resulting from our having to re-perform certain services provided by Scottish Biomedical and for losses we suffered as a result of delays to the advancement of our programs.

On September 21, 2009, our former chief financial officer, Richard J. Klein, filed a lawsuit against us and 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 October 13, 2009 we filed a motion with the court seeking dismissal of all claims against all of the individual defendants named in Mr. Klein s complaint. We intend to vigorously defend 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.

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

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development and commercialization of our lead product candidate, OMS103HP, for use during arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery as well as arthroscopic meniscectomy surgery. We have not yet obtained regulatory approval to market this product candidate for ACL reconstruction surgery, arthroscopic 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. If OMS103HP does not receive regulatory approval for ACL reconstruction surgery or arthroscopic meniscectomy surgery, 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 2011 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 currently conducting a Phase 2 concentration-ranging clinical trial to assist in determining the optimal concentration of the mydriatic API contained in OMS302 as a mydriasis induction agent in patients undergoing cataract surgery. We are also conducting 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 $3.9 million and $7.4 million for the three months ended September 30, 2009 and 2008, respectively, and $15.5 million and $17.4 million for the nine months ended September 30, 2009 and 2008, respectively. As of September 30, 2009, we had an accumulated deficit of approximately $112.8 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 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.

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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. 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.

If our clinical trials are delayed, we may be unable to develop our product candidates on a timely basis, which may increase our development costs and could 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;

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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 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.

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

- complete the Phase 3 clinical trials of OMS103HP for use in arthroscopic ACL reconstruction surgery;
- initiate, conduct and complete the Phase 3 clinical trials of OMS103HP for use in arthroscopic 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 beyond what we raised in our October 2009 IPO to complete the clinical development and commercialization of OMS103HP and to decrease spending on our other clinical and preclinical development programs. We have no commitments for additional funding 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, our shareholders may experience significant dilution. Any debt financing, if available, may restrict our operations as further described in the following risk factor. 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 relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves. Any of these events could significantly harm our business and prospects and could cause our stock price to decline.

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

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in our business or competitive activities. In addition, if we default under our agreement, BlueCrest may have the right to accelerate all of our repayment obligations under the agreement and to take control of our pledged assets, which include our cash, cash equivalents and short-term investments, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. 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. Although we believe that the breadth of our clinical and preclinical programs makes it unlikely that any single event would impact our viability, BlueCrest could nonetheless declare a default upon the occurrence of any event that it interprets as having a material adverse effect upon us as defined under our agreement, thereby requiring us 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 insurance coverage.

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,

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third-party payors and other members of the medical community, it is unlikely that we will ever become profitable, and if we are unable to increase market penetration of 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. For example, we engaged Scottish Biomedical, Ltd., or SBM, to assist us in developing compounds for our PDE10 and PDE7 programs. We believe that, among other things, SBM breached its obligations under our agreement and committed fraud, requiring us to re-perform certain services provided by SBM and delaying the advancement of our programs.

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 have no experience in the sales, marketing and distribution of biopharmaceutical products. Developing an internal sales force is expensive and time-consuming and should be commenced 12 to 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.

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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 have been manufactured in a freeze-dried, or lyophilized, form by Catalent Pharma Solutions, Inc. in its Albuquerque, New Mexico facility. In May 2008, Catalent announced that it sold this facility to OSO Biopharmaceuticals Manufacturing, LLC, or OSO. OSO announced that it intends to continue the manufacture of 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 an additional registration batch 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 and may require us to conduct additional studies, which we expect would be nonclinical and/or clinical pharmacokinetic studies, to demonstrate that liquid OMS103HP is as safe and effective as lyophilized OMS103HP. Delays or unexpected results in these 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.

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

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

We must purchase from third-party suppliers the ingredients necessary for our contract manufacturers to produce our PharmacoSurgery product candidates for our clinical trials and, if approved, for commercial distribution. Suppliers may not sell these ingredients to us at the time we need them or on commercially reasonable terms, if at all. Although we intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of ingredients for our PharmacoSurgery product candidates, we have not yet entered into and we may be unable to secure any such supply agreements or guarantees. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients in a timely manner or in the minimum guaranteed quantities. If 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 are likely to use proprietary active ingredients in some product candidates that we develop from our PDE7 program and possibly 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 programs. 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 and from the UK Medical Research Council, or MRC. The continued maintenance of these agreements requires us to undertake development activities if and when a clinical candidate has been selected and, if regulatory approval for marketing is obtained, to pay royalties to the University of Leicester and MRC upon commercialization of a MASP-2 product candidate. 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.

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Our ability to pursue the development and commercialization of product candidates from our MASP-2 program could be jeopardized by third-party patent rights.

Our MASP-2 program is based in part on the results of research conducted by collaborators at MRC, the University of Leicester and Aarhus Universitet, and on intellectual property rights that we licensed on a worldwide exclusive basis from the University of Leicester and from MRC stemming from that collaborative research and from subsequent research performed by the University of Leicester and by MRC. Researchers at Aarhus Universitet have obtained a U.S. Patent that claims antibodies that bind MASP-2, and have filed other patents and patent applications related to MASP-2. While we do not hold any direct license from Aarhus Universitet or its researchers, our license from MRC includes MRC s joint ownership interest in this U.S. Patent claiming antibodies that bind MASP-2, which joint ownership inter