OMEROS CORP
Form 10-Q
May 12, 2014
Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2014

or

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

For the transition period from to

Commission file number: 001-34475

OMEROS CORPORATION
(Exact name of registrant as specified in its charter)

Washington (State or other jurisdiction of incorporation or organization)	91-1663741 (I.R.S. Employer Identification Number)
201 Elliott Avenue West Seattle, Washington (Address of principal executive offices) (206) 676-5000 (Registrant's telephone number, including area code)	98119 (Zip Code)

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

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

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

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

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

As of May 7, 2014, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 33,912,447.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 which are subject to the "safe harbor" created by those sections for such statements. 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 fact are "forward-looking statements." Terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "may," "plan," "potential," "predict," "project," "should," "will," "would," and similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

- our ability to receive regulatory approval for our New Drug Application, or NDA, and our Marketing Authorisation Application, or MAA, for OMS302, or Omidria,™ in the United States and in the European Union, or EU, respectively, in 2014;
- our expectation that the U.S. Food and Drug Administration will approve our NDA for Omidria in the second quarter of 2014;
- our anticipation that we will begin marketing Omidria, if approved, in the U.S. in the second half of 2014, and that we will initiate marketing of Omidria, assuming approval of our MAA for Omidria by the European Medicines Agency and partnering in Europe, in the EU in late 2014 or the first half of 2015;
- our plans for sales, marketing and distribution of Omidria in the U.S., EU and other international territories;
- our ability to successfully complete our Phase 2 clinical trials for OMS824 and OMS721;
- our expectation of timing for enrollment of patients in our Phase 2 clinical trial for OMS721;
- our ability to initiate post-marketing studies for Omidria and additional clinical trials for OMS103, should they be necessary;
- whether there may be an opportunity to have OMS103 produced and commercialized by a registered outsourcing facility;
- our expectations regarding the clinical, therapeutic and competitive benefits of our potential products, which we refer to herein as products;
- our estimate regarding how long our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments;
- our ability to raise additional capital through the capital markets or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;
- our expectation that the second half of 2014 is the earliest period in which any of our products will be commercially available or generate revenue;
- our anticipation that we will rely on contract manufacturers to develop and manufacture our products for commercial sale;
- our ability to enter into acceptable arrangements with potential corporate partners;
- whether pediatric studies may afford Omidria an additional six months of exclusivity;
- whether OMS824 has the potential to be delivered as monotherapy or as an adjunct to commercially available antipsychotics;
- whether GPR17 may play a role in re-myelination of neurons and whether GPR17 could be an important drug target in the treatment of demyelinating disorders;
- our expectations about the commercial competition that our products may face;
- our expected financial position, performance, growth, expenses, magnitude of net losses and availability of resources;
- the extent of protection that our patents provide and that our pending patent applications will provide, if patents issue from such applications, for our technologies, programs and products;
- our involvement in potential claims, legal proceedings and administrative actions, the expected course and costs of potential claims, legal proceedings and administrative actions, and the potential outcomes and effects of potential claims, legal proceedings and administrative actions on our business, prospects, financial condition and results of operations; and
-

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

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

Table of Contents

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

Table of Contents

OMEROS CORPORATION
FORM 10-Q FOR THE QUARTER ENDED March 31, 2014
INDEX

Table of Contents

PART I—FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
OMEROS CORPORATION
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	March 31, 2014 (unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$567	$ 1,384
Short-term investments	51,622	12,717
Grant and other receivables	488	379
Prepaid expenses	1,312	251
Other current assets	143	86
Total current assets	54,132	14,817
Property and equipment, net	989	939
Restricted cash	679	679
Other assets	267	100
Total assets	$56,067	$ 16,535
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$4,926	$ 2,329
Accrued expenses	5,306	3,944
Current portion of notes payable, net of discount	—	5,600
Total current liabilities	10,232	11,873
Notes payable, net of current portion and discount	32,212	14,898
Deferred rent	8,411	8,148
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Preferred stock, par value $0.01 per share:		
Authorized shares—20,000,000 at March 31, 2014 (unaudited) and December 31, 2013;		
Issued and outstanding shares—none	—	—
Common stock, par value $0.01 per share:		
Authorized shares—150,000,000 at March 31, 2014 (unaudited) and December 31, 2013;		
Issued and outstanding shares—33,901,591 and 30,359,508 at March 31, 2014 (unaudited) and December 31, 2013, respectively	339	304
Additional paid-in capital	275,888	235,685
Accumulated deficit	(271,015)	(254,373)
Total shareholders' equity (deficit)	5,212	(18,384)
Total liabilities and shareholders' equity	$56,067	$ 16,535

See notes to consolidated financial statements

Table of Contents

OMEROS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2014	2013
Revenue	$100	$1,095
Operating expenses:		
Research and development	12,017	7,127
Selling, general and administrative	3,767	3,988
Total operating expenses	15,784	11,115
Loss from operations	(15,684)	(10,020)
Investment income	2	6
Interest expense	(672)	(587)
Other income (expense), net	(288)	112
Net loss	$(16,642)	$(10,489)
Comprehensive loss	$(16,642)	$(10,489)
Basic and diluted net loss per share	$(0.54)	$(0.40)
Weighted-average shares used to compute basic and diluted net loss per share	30,897,039	25,908,153

See notes to consolidated financial statements

Table of Contents

OMEROS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(unaudited)

	Three Months Ended March 31,	
	2014	2013
Operating activities:		
Net loss	$(16,642)	$(10,489)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of assets	(9)	—
Depreciation and amortization	82	67
Stock-based compensation expense	1,788	1,093
Non-cash interest expense	136	120
Warrant modification expense	452	41
Changes in operating assets and liabilities:		
Grant and other receivables	(109)	(69)
Prepaid expenses and other current and noncurrent assets	(1,060)	(75)
Accounts payable and accrued expenses	3,960	1,227
Deferred revenue	—	(970)
Deferred Rent	263	87
Net cash used in operating activities	(11,139)	(8,968)
Investing activities:		
Purchases of property and equipment	(6)	(88)
Purchases of investments	(58,839)	(3,455)
Proceeds from the sale of investments	19,934	12,250
Net cash provided by (used in) investing activities	(38,911)	8,707
Financing activities:		
Proceeds from issuance of common stock, net of offering costs	37,749	—
Net proceeds from borrowings under notes payable	12,699	—
Payments on notes payable	(1,464)	—
Proceeds from issuance of common stock upon exercise of stock options	249	22
Net cash provided by financing activities	49,233	22
Net decrease in cash and cash equivalents	(817)	(239)
Cash and cash equivalents at beginning of period	1,384	1,520
Cash and cash equivalents at end of period	$567	$1,281
Supplemental cash flow information		
Cash paid for interest	$691	$313

See notes to consolidated financial statements

Table of Contents

OMEROS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced potential product, OMS302 or Omidria™ for lens replacement surgery, is derived from our proprietary PharmacoSurgery® platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical 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 inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. In addition to Omidria, we have six other clinical-stage development programs in our pipeline, which also includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor (GPCR) drug targets and the other used to generate antibodies. For each of our programs and potential products, which we refer to herein as products, we have retained all manufacturing, marketing and distribution rights.

Omidria is being developed for use in patients undergoing intraocular lens replacement surgery. In July 2013, we submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and in September 2013, we submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Omidria. We expect the FDA to approve our NDA for Omidria in the second quarter of 2014. Assuming approval, we expect to begin marketing Omidria in the U.S. in the second half of 2014. In the European Union (EU) and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria.

Basis of Presentation

Our consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions between and among our subsidiaries have been eliminated. The accompanying unaudited consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of March 31, 2014 and for the three months ended March 31, 2014 and 2013 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Consolidated Balance Sheet at December 31, 2013 has been derived from audited financial statements but does not include all of the information and footnotes required by GAAP.

The accompanying unaudited consolidated financial statements and notes to consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto that are included in our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission (SEC) on March 13, 2014.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant items subject to such estimates include revenue recognition, fair market value of investments, stock-based compensation expense and accruals for clinical trials and contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from these estimates.

Liquidity and Capital Resources

As of March 31, 2014, we had $52.2 million in cash, cash equivalents and short-term investments due, in part, to our recent receipt of the net amounts of $37.7 million from the sale of our common stock and $12.7 million of additional debt financing. We believe that our existing cash, cash equivalents and short-term investments, together with potential sales from Omidria and capital that we may be able to raise through one or more corporate partnerships, equity

offerings, debt financings, collaborations, licensing arrangements or asset sales, will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months.

Table of Contents

Inventory

Capitalization of costs as inventory will begin when the product has received regulatory approval in either the U.S. or the EU. We expense inventory costs related to products as research and development expenses prior to regulatory approval.

Segments

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

Note 2—Net Loss Per Share

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

The basic and diluted net loss per share amounts for the three months ended March 31, 2014 and 2013 were computed based on the shares of common stock outstanding during the respective periods. Potentially dilutive securities excluded from the diluted loss per share calculation are as follows:

	March 31,	
	2014	2013
Outstanding options to purchase common stock	6,762,948	5,356,086
Warrants to purchase common stock	609,016	609,016
Total	7,371,964	5,965,102

Note 3—Cash, Cash Equivalents and Investments

As of March 31, 2014 and December 31, 2013, all investments are classified as short-term and available-for-sale on the accompanying Consolidated Balance Sheets. We did not own any securities with unrealized loss positions as of March 31, 2014 or December 31, 2013. Investment income consists primarily of interest income.

Note 4—Fair-Value Measurements

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

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

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

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

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

	March 31, 2014			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as cash equivalents	$—	$—	$—	$—
Money-market funds classified as non-current restricted cash	679	—	—	679
Money-market funds classified as short-term investments	51,622	—	—	51,622
Total	$52,301	$—	$—	$52,301

Table of Contents

	December 31, 2013			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as cash equivalents	$213	$—	$—	$213
Money-market funds classified as non-current restricted cash	679	—	—	679
Money-market funds classified as short-term investments	12,717	—	—	12,717
Total	$13,609	$—	$—	$13,609

Cash held in demand deposit accounts of $567,000 and $1.2 million is excluded from our fair-value hierarchy disclosure as of March 31, 2014 and December 31, 2013, respectively. There were no unrealized gains and losses associated with our short-term investments as of March 31, 2014 or December 31, 2013. The carrying amounts reported in the accompanying Consolidated Balance Sheets for grant and other receivables, accounts payable and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

Note 5—Accrued Liabilities

Accrued liabilities consisted of the following:

	March 31, 2014	December 31, 2013
	(In thousands)	
Contract research	$1,727	$858
Employee compensation	1,476	1,346
Clinical trials	768	596
Consulting & professional fees	971	649
Other accruals	364	495
Total accrued liabilities	$5,306	$3,944

Note 6—Notes Payable

In March 2014, we entered into a new Loan and Security Agreement (the Oxford/MidCap Loan Agreement) with Oxford Finance LLC (Oxford) and MidCap Financial SBIC, LP (MidCap) pursuant to which we borrowed $32.0 million. We used approximately $19.1 million of the loan proceeds to repay all of the amounts owed by us under our then outstanding loan from Oxford and, after deducting all loan initiation costs including a $160,000 upfront loan initiation fee and lenders' legal costs, we received $12.7 million in net proceeds. The Oxford/MidCap Loan Agreement provides for monthly interest-only payments at an annual rate of 9.25% through March 1, 2015. Beginning April 1, 2015, monthly principal and interest payments of $1.0 million are due through the maturity date of March 1, 2018. In addition, the Oxford/MidCap Loan Agreement requires a $2.2 million loan maturity fee upon full repayment of the loan. We may prepay the outstanding principal balance in its entirety at any time if we pay an additional fee equal to 1.0% of the then-outstanding principal balance, which prepayment fee would be waived if we refinance the indebtedness with Oxford and MidCap and pay the loan maturity fee. As security under the Oxford/MidCap Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property.

The Oxford/MidCap Loan Agreement contains covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, pledge our intellectual property or repurchase stock. Additionally, the Oxford/MidCap Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breach, occurrence of a material adverse effect (MAE, as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgment defaults and a change of control. The occurrence

of an event of default could result in the acceleration of the Oxford/MidCap Loan Agreement and, under certain circumstances, could increase our interest rate 5.0% per annum during the period of default.

MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our

Table of Contents

inability to repay any portion of the loans in accordance with the terms of the Oxford/MidCap Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the enforceability of any material provision of the Oxford/MidCap Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce its rights and remedies under the Oxford/MidCap Loan Agreement or related agreements.

We accounted for the Oxford/MidCap Loan Agreement as a debt modification and, accordingly, the remaining unamortized debt issuance costs of $103,000 associated with the then outstanding loan with Oxford and the debt issuance costs of $244,000 associated with the Oxford/MidCap Loan Agreement are being amortized to interest expense using the effective interest method through the March 1, 2018 Oxford/MidCap Loan Agreement maturity date. Additionally, the $2.2 million maturity fee, which is treated as a debt discount, is being amortized to interest expense using the effective-interest method through March 1, 2018.

As of March 31, 2014, the remaining unamortized discount and debt issuance costs associated with the debt were $2.2 million and $339,000, respectively.

Note 7—Revenue

Revenue recognized from grants and other sources is as follows:

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Small Business Innovative Research Grants	$100	$125
Vulcan Inc.	$—	$970
Total revenue	$100	$1,095

We have periodically received Small Business Innovative Research (SBIR) grants from the National Institutes of Health (NIH), which are used to support the research and development of our products. We recorded revenue related to these grants of $100,000 and $125,000 for the three months ended March 31, 2014 and 2013, respectively. As of March 31, 2014, $1.1 million of potential revenue remained available under these grants, if qualifying research is performed.

In October 2010, we entered into a platform development funding agreement with Vulcan Inc. and its affiliate (collectively, Vulcan) pursuant to which we received $20.0 million for our G protein-coupled receptor (GPCR) program. Of the funds received, $8.2 million was recorded as deferred revenue. The remaining deferred revenue of $970,000 was recognized as revenue during the first quarter of 2013.

Note 8—Commitments and Contingencies

Real Estate Obligations

We currently lease our office and laboratory space in The Omeros Building under a lease agreement with BMR-201 Elliott Avenue LLC (BMR). The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of March 31, 2014, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately $61.0 million. The remaining deferred rent balance relates to rent deferrals since the inception of our lease. Deferred rent is being amortized to research and development and selling, general and administrative expense on a straight-line basis through the term of the lease.

Development Milestones and Product Royalties

We have retained the worldwide commercial rights to all of the products in our clinical and preclinical programs. We potentially owe certain development milestones and sales based royalties on commercial sales of certain products within our pipeline. These are low-single-digit royalties based on net sales or net income as more fully described in our 2013 Annual Report on Form 10-K filed with the SEC on March 13, 2014.

In April 2010, we entered into an exclusive license agreement with Helion Biotech ApS (Helion), pursuant to which we received a royalty-bearing, worldwide exclusive license to all of Helion's intellectual property rights related to mannan-binding lectin-associated serine protease-2 (MASP-2) antibodies, polypeptides and methods in the field of

inhibition of mannan-binding lectin-mediated activation of the complement system for the prevention, treatment or diagnosis of any disease or condition. We

Table of Contents

incurred a milestone payment of $200,000 to Helion during the first quarter of 2014 related to the filing of an Investigational New Drug Application (IND) with the FDA.

Other

In the first quarter of 2013, we recorded a $900,000 expense as selling, general and administrative expense in connection with previously awarded NIH grants.

Note 9—Shareholders' Equity

Common Stock

Public Offering - In March 2014, we sold 3.5 million shares of our common stock at a public offering price of $11.50 per share in a public offering. After deducting offering expenses and underwriter discounts of $2.5 million, we received net proceeds from the transaction of $37.7 million.

MLV At-the-Market Sales Agreement - In December 2012, we entered into an at-the-market issuance sales agreement (the Sales Agreement) with MLV & Co. LLC (MLV). The Sales Agreement terminated April 16, 2014.

Warrants

The following table summarizes our total outstanding warrants as of March 31, 2014, which have a weighted average exercise price of $23.85:

Outstanding At March 31, 2014	Expiration Date	Exercise Price
197,478	September 29, 2014	$12.25
133,333	October 21, 2015	20.00
133,333	October 21, 2015	30.00
133,333	October 21, 2015	40.00
11,539	April 26, 2015	9.13
609,016		$23.85

On March 28, 2014, we extended the expiration dates of warrants to purchase 197,478 shares of our common stock at an exercise price of $12.25 per share to September 29, 2014. In March 2013, we extended the expiration dates of the same warrants by one year. We evaluated the fair value of the warrants before and after the modifications and recorded the $452,000 and $41,000 change in fair value as other expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the three months ended March 31, 2014 and 2013, respectively.

In October 2010, in connection with the Vulcan agreement, we issued to Vulcan three warrants to purchase our common stock, each with a five-year term and exercisable for 133,333 shares, with exercise prices of $20, $30 and $40 per share, respectively.

Note 10—Stock-Based Compensation

Our 2008 Equity Incentive Plan (the 2008 Plan) provides for the grant of incentive and nonstatutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, directors and consultants and subsidiary corporations' employees and consultants. Options are granted with exercise prices equal to the closing fair market value of our common stock on the date of the grant. The terms of options may not exceed 10 years and options generally vest over a four-year period.

On January 1, 2014, in accordance with provisions of the 2008 Plan, the authorized shares available for grant under the 2008 Plan were increased by 1,517,975 shares. As of March 31, 2014, a total of 8,858,525 shares were reserved for issuance under our stock plans, of which 2,095,577 were available for future grants under the 2008 Plan.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. There were no stock option grants during the first quarter of 2014 or 2013.

Table of Contents

Stock-based compensation expense has been reported in our Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Research and development	$1,011	$581
Selling, general and administrative	777	512
Total	$1,788	$1,093

Stock option activity for all stock plans and related information is as follows:

	Options Outstanding	Weighted-Average Exercise Price per Share	Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2013	6,969,303	$6.38		
Granted	—	—		
Exercised	(42,083)	5.93		
Forfeited	(164,272)	9.80		
Balance at March 31, 2014	6,762,948	$6.30	6.83	$39,056
Vested and expected to vest at March 31, 2014	6,526,397	$6.20	6.75	$38,315
Exercisable at March 31, 2014	4,322,288	$4.78	5.63	$31,509

At March 31, 2014, there were 2,440,660 unvested options outstanding that will vest over a weighted-average period of 2.3 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these options is $12.9 million.

Table of Contents

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

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

Overview

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced potential product, OMS302 or Omidria™ for intraocular lens replacement, or ILR, is derived from our proprietary PharmacoSurgery® platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical 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 inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. In addition to Omidria, we have six other clinical-stage development programs in our pipeline, which also includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor, or GPCR, drug targets and the other used to generate antibodies. For each of our programs and potential products, which we refer to herein as products, we have retained all manufacturing, marketing and distribution rights.

Products and Development Programs

We submitted for Omidria a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, in July 2013 and a Marketing Authorisation Application, or MAA, to the European Medicines Agency, or EMA, in September 2013 to allow us to market and sell Omidria in the U.S. and the European Union, or EU, respectively, for use in patients undergoing ILR. In October 2013, we announced that the FDA accepted the NDA for Omidria for filing and that the MAA for Omidria was validated by the EMA. We expect the FDA to approve our NDA for Omidria in the second quarter of 2014. Assuming approval, we expect to begin marketing Omidria in the U.S. in the second half of 2014. In November 2013, the FDA conditionally accepted Omidria as the proposed brand name for OMS302 in the U.S. and in December 2013, the EMA accepted Omidria as the proposed brand name for OMS302 in the EU. These acceptances are subject to final determination prior to approval of the respective marketing applications. For the potential commercial launch of Omidria in the U.S., if approved, we intend to develop our own internal sales and marketing management team and to utilize marketing consultants and a contract sales organization to call on surgeons, hospitals and ambulatory surgery centers in the U.S. In the EU and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria. Assuming approval of our MAA for Omidria by the EMA and partnering in Europe, we anticipate the initiation of EU marketing and sales of Omidria in late 2014 or in the first half of 2015. We have discussed with the FDA and EMA the design for pediatric studies for Omidria, which may afford Omidria an additional six months of exclusivity in each of these territories if completed successfully. In addition, we are exploring the potential role of Omidria in the management of intraoperative floppy iris syndrome, or IFIS.

Behind Omidria in our pipeline, we have a series of other development programs targeting pain, inflammation, coagulopathies and disorders of the central nervous system. We have the following six additional clinical-stage programs in our pipeline: (1) OMS103 for reducing inflammatory pain following arthroscopic partial meniscectomy, which has completed one Phase 3 trial in patients undergoing this procedure, (2) our lead phosphodiesterase 10, or PDE10, inhibitor OMS824 for the treatment of schizophrenia, which is in a Phase 2 clinical program, (3) our lead PDE10 inhibitor OMS824 for the treatment of Huntington's disease, which is in a Phase 2 clinical program, (4) our lead MASP-2 antibody OMS721, which is in a Phase 2 clinical program in patients with thrombotic microangiopathies, or TMAs, (5) our PPAR program, in which three Phase 2 clinical trials are being conducted by our collaborators to evaluate a PPAR agonist, alone or in combination with other agents, for their effects on smoking, as well as in the abuse liability of oxycodone or heroin and (6) our PharmacoSurgery product OMS201 for use during urological procedures, including uroendoscopic procedures, which has completed a Phase 1/Phase 2 clinical trial in 2010 and is not currently in active clinical trials. Of these six additional clinical programs, we currently are focused on OMS103, OMS824 and OMS721.

OMS103, our second PharmacoSurgery product, is being developed for use during arthroscopic procedures, including partial meniscectomy surgery. We are redesigning our Phase 3 clinical program in arthroscopic partial meniscectomy surgery to include reduction of early postoperative pain as the primary endpoint. In addition, we are evaluating alternative approaches for making OMS103 commercially available, such as through a registered outsourcing facility without the need to conduct any additional clinical trials.

OMS824 is in two Phase 2 clinical programs, one for schizophrenia and one for Huntington's disease. We are conducting an ongoing Phase 1 clinical program evaluating the safety, tolerability and pharmacokinetics of OMS824 in healthy subjects as

Table of Contents

well as a clinical trial to evaluate target occupancy of OMS824 using PET scans in healthy subjects by measuring the extent to which OMS824 binds to PDE10 in the brain. In January 2014, we announced positive results from our OMS824 Phase 2a clinical trial in which OMS824 was well tolerated and demonstrated comparable tolerability and systemic pharmacokinetics when administered alone and concomitantly with approved antipsychotic agents in patients with stable schizophrenia, opening the potential for OMS824 to be delivered as monotherapy or as an adjunct to commercially available antipsychotics. OMS824 has received Orphan Drug designation for the treatment of Huntington's disease and Fast Track designation for the treatment of cognitive impairment in patients with Huntington's disease. We also are seeking Fast Track designation for OMS824 for schizophrenia.

For OMS721, in February 2014 we reported positive data from our Phase 1 clinical trial. In March 2014, we submitted to the FDA an IND application to evaluate OMS721 in patients with complement-mediated TMAs. That same month, we announced positive data using OMS721 in ex vivo studies of endothelial activation relevant to the pathophysiology of human atypical hemolytic uremic syndrome, or aHUS, a form of TMA. These studies showed that OMS721 significantly inhibited complement deposition in the system using serum samples from aHUS patients obtained during the acute phase of disease ($p<0.01$) and during remission ($p<0.001$) compared to untreated controls. In April 2014, the IND was cleared by the FDA, and a Phase 2 clinical program is currently underway with enrollment of TMA patients expected to begin later this quarter. OMS721 has received Orphan Drug designation for inhibition of complement-mediated TMAs.

Our preclinical programs include: (1) our PDE7 program in which we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders, (2) our Plasmin program in which we are advancing novel antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma as well as for other hyperfibrinolytic states (e.g., liver disease), (3) our proprietary ex vivo antibody platform and (4) our orphan GPCR platform in which we are working to complete high-throughput surrogate de-orphanization of orphan GPCRs, identifying small-molecule compounds that bind and functionally interact with the receptors and to develop products that act at these new potential drug targets. To date, we have identified and confirmed sets of small-molecule compounds that interact selectively with, and modulate signaling of, 54 Class A orphan GPCRs, as well as two Class B GPCRs (glucagon-like peptide-1 receptor, or GLP-1R, and parathyroid hormone 1 receptor, or PTH-1R). We have initiated medicinal chemistry efforts to optimize compounds against several orphan GPCRs including GPR17, which appears to play a critical role in re-myelination of neurons and could be an important drug target in the treatment of demyelinating disorders such as multiple sclerosis as well as traumatic brain and spinal cord injuries.

Financial Summary

The majority of our operating expenses to date have been for research and development activities. Research and development expenses consist of costs associated with research activities as well as costs associated with our product development efforts, which include clinical trial and third-party manufacturing services. Internal research and development costs are recognized as incurred. Third-party research and development costs are expensed at the earlier of when the contracted work has been performed or when upfront and milestone payments are made. Research and development expenses include:

- employee and consultant-related expenses, which include salaries and benefits, and non-cash stock-compensation;
- external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, clinical research organizations, or CROs, clinical trial sites, and collaborators or licensors;
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and depreciation of leasehold improvements and equipment; and
- third-party supplier expenses including laboratory and other supplies.

We recognized net losses of $16.6 million and $10.5 million for the three months ended March 31, 2014 and 2013, respectively. These losses have resulted principally from expenses incurred in connection with research and development activities, consisting primarily of clinical trials, manufacturing services and preclinical studies associated with our current products. Compared to 2013, we expect our net losses to increase as we continue to add personnel for our anticipated growth and to prepare for the commercial launch of Omidria in the U.S., if it is approved, to advance our clinical trials, and expand our research and development efforts. As of March 31, 2014, our accumulated deficit was $271.0 million, total shareholders' equity was $5.2 million and we had $52.2 million in cash, cash equivalents and

short-term investments.

Table of Contents

Results of Operations

Revenue

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Small Business Innovative Research Grant	$100	$125
Vulcan Inc.	—	970
Total Revenue	$100	$1,095

Historically, our revenue has consisted of grant funding and revenue recognized in connection with funding received from third parties. Other than grant funding, we do not expect to receive any revenue from our products unless we receive regulatory approval and commercialize our products or enter into collaborative agreements for the development and commercialization of our products. Omidria, our most advanced product, is currently under review for marketing authorization by both the FDA and the EMA. We expect the FDA to approve our NDA for Omidria in the second quarter of 2014. We do not expect Omidria to be commercially available, if at all, before the second half of 2014 in the U.S. and late in 2014 or in the first half of 2015 in Europe. With respect to the EU, we do not expect to begin marketing Omidria until we have secured a partner with European commercial operations. We continue to pursue government and private grant funding as well as collaboration funding for our products and research programs. The decrease in revenue during the three months ended March 31, 2014 was due to lower revenue recognized from our GPCR program funding agreement with Vulcan Inc. and its affiliate, which we collectively refer to as Vulcan. We recognized the remaining deferred revenue in connection with the Vulcan agreement as revenue in the first quarter of 2013. No further revenue remains to be recognized under the agreement as of March 31, 2014.

Research and Development Expenses

Our research and development expenses can be divided into direct external expenses, which include clinical research and development and preclinical research and development activities; internal, overhead and other expenses; and stock-based compensation expense. The following table illustrates our expenses associated with these activities:

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Direct external expenses:		
Clinical research and development:		
OMS824	$3,620	$374
OMS721	2,033	—
Omidria	1,139	887
OMS103	16	266
Other clinical programs	8	11
Total clinical research and development	6,816	1,538
Preclinical research and development	312	1,600
Total direct external expenses	7,128	3,138
Internal, overhead and other expenses	3,878	3,408
Stock-based compensation expense	1,011	581
Total research and development expenses	$12,017	$7,127

The increase in total research and development expenses during the three months ended March 31, 2014 compared to the same quarter in the prior year was due primarily to higher clinical material manufacturing and clinical expenses related to our Phase 1 and Phase 2 clinical trials evaluating OMS824 for the treatment of schizophrenia and Huntington’s disease, higher clinical material manufacturing and clinical expenses related to our Phase 2 clinical trial

evaluating OMS721 in patients with TMAs, higher expense related to non-cash stock compensation, and higher employee costs. Non-cash stock compensation

Table of Contents

expense increased for the three months ended March 31, 2014 compared to the same period in 2013 due to the grant of stock options during the third quarter of 2013 related to annual performance reviews. These increased expenses for the three months ended March 31, 2014 compared to the same period in 2013 were partially offset by lower clinical research and development expenses related to reduced preclinical activity on our PDE7 program and the completion of our OMS103 Phase 3 clinical trial in December 2012, for which there were costs related to close out during the first quarter of 2013. We expect our research and development expenses to remain constant or increase slightly in the near term as we continue to advance OMS824, OMS721, OMS302 and OMS103 through further clinical development and initiate clinical trials for our Plasmin and PDE7 programs.

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

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

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

Selling, General and Administrative Expenses

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Selling, general and administrative, excluding stock-based compensation expense	$2,990	$3,476
Stock-based compensation expense	777	512
Total selling, general and administrative expenses	$3,767	$3,988

The decrease in selling, general and administrative expenses during the three months ended March 31, 2014 was primarily due to a $900,000 expense recorded in the first quarter of 2013 in connection with previously awarded grants from the National Institutes of Health, or NIH. Exclusive of the NIH expense, selling, general and administrative expenses increased from the first quarter of 2013 compared to the same quarter in 2014. This increase was primarily due to non-cash stock compensation costs and expenses related to the preparation for our planned commercial launch of Omidria in the U.S. We expect our selling, general and administrative expenses to increase in the near term as we prepare for the potential commercial launch of Omidria in the second half of 2014.

Interest Expense

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Interest expense	$672	$587

Table of Contents

The increase in interest expense during the three months ended March 31, 2014 was due primarily to a higher average balance on our note payable during the 2014 period due to entering into a new loan agreement, or the Oxford/MidCap Loan Agreement, with Oxford and MidCap Financial SBIC, LP, or MidCap, in March 2014, pursuant to which we increased the aggregate amount of our outstanding indebtedness.

Other Income (Expense), Net

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Other income (expense), net	$(288)	$112

Other income (expense) principally includes rental income and costs associated with warrant modifications. The decrease in other income (expense) during the three months ended March 31, 2014 is due to an increase in warrant modification expenses from $41,000 in the first quarter of 2013 to $452,000 in the same quarter in 2014 when we extended the exercise period of these warrants by one year and six months, respectively. The warrant modification expenses in each period relate to extensions of the expiration dates of these warrants to purchase up to 197,478 shares of common stock in aggregate.

Financial Condition - Liquidity and Capital Resources

As of March 31, 2014, we had $52.2 million in cash, cash equivalents and short-term investments that are held principally in interest-bearing instruments, including money-market accounts. Cash in excess of our immediate requirements is invested in accordance with established guidelines to preserve principal and maintain liquidity.

In March 2014, we sold 3.5 million shares of our common stock in a public offering at a public offering price of $11.50 per share. After deducting offering expenses and underwriter discounts, we received net pro