OMEROS CORP
Form 10-Q
August 09, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2018

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)
201 Elliott Avenue West Seattle, Washington	98119
(Address of principal executive offices)	(Zip Code)

(206) 676-5000
(Registrant's telephone number, including area code)

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

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 o

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

Large accelerated filer	x	Accelerated filer	o
Non-accelerated filer	o (Do not check if a smaller reporting company)	Smaller reporting company	o
Emerging growth company	o		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the

Exchange Act. 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 x

As of August 6, 2018, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 48,559,816.

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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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act, 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," "intend," "likely," "may," "plan," "potential," "predict," "projec "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 expectations relating to demand for OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% from wholesalers, ambulatory surgery centers, or ASCs, and hospitals, and our expectations regarding OMIDRIA product sales, including once pass-through reimbursement status is reinstated pursuant to the Consolidated Appropriations Act, 2018, or the Appropriations Act;
- our estimates of OMIDRIA chargebacks and rebates, distribution fees and product returns;
- our estimates regarding how long our existing cash, cash equivalents, short-term investments and revenues will be sufficient to fund our anticipated operating expenses and capital expenditures, as well as our interest and principal payments on our outstanding notes under our Term Loan Agreement, or the CRG Loan Agreement, with CRG Servicing LLC, or CRG, and the lenders identified therein, and the satisfaction of covenants thereunder;
- our expectations regarding the clinical, therapeutic and competitive benefits and importance of OMIDRIA and our product candidates;
- our expectations related to obtaining permanent separate or similar reimbursement for OMIDRIA from the Centers for Medicare and Medicaid Services, or CMS, and/or from Congress, particularly after September 30, 2020;
- our ability to design, initiate and/or successfully complete clinical trials and other studies for our products and product candidates and our plans and expectations regarding our clinical trials, including our clinical trials for OMS721, for OMS906 and for OMS527;
- in our OMS721 program, our expectations regarding: whether enrollment in any or all ongoing and planned Phase 3 clinical trials will proceed as expected; whether accelerated approval, fast track designation, breakthrough therapy designation and/or orphan drug designation may be granted by the U.S. Food and Drug Administration, or FDA, or Priority Medicines status, conditional marketing authorization or orphan designation may be granted by the European Medicines Agency, or EMA, for indications for which we are pursuing such approval or designation; whether and when a Biologics License Application, or BLA, for accelerated approval of OMS721 may be filed with the FDA and whether the FDA will grant accelerated or full approval for OMS721; paths to accelerated and full approval of OMS721 in hematopoietic stem cell transplant-associated thrombotic microangiopathy, or HSCT-TMA; and potential approval with respect to our Phase 3 clinical trial for patients with Immunoglobulin A, or IgA, nephropathy;
- our anticipation that we will rely on contract manufacturers to manufacture OMIDRIA for commercial sale and to manufacture our product candidates for clinical trial supply and, if approved, for commercial sale;
- our ability to enter into acceptable arrangements with potential corporate partners or contract service providers, including with respect to OMIDRIA, and our ability and plans to effect any such arrangements with respect to OMIDRIA in the European Union, or EU, or in other foreign countries;
- 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 expectations about the commercial competition that OMIDRIA and our product candidates, if commercialized, face or may face;
- the expected course and costs of existing claims, legal proceedings and administrative actions, our involvement in potential claims, legal proceedings and administrative actions, and the merits, potential outcomes and effects of both existing and potential claims, legal proceedings and administrative actions, as well as regulatory determinations, on our business, prospects, financial condition and results of operations;
-

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, products and product candidates;

- the factors on which we base our estimates for accounting purposes and our expectations regarding the effect of changes in accounting guidance or standards on our operating results; and
- our expected financial position, performance, revenues, growth, costs and expenses, magnitude of net losses and the availability of resources.

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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 headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in our other filings with the Securities and Exchange Commission, or SEC. Given these risks, uncertainties and other factors, actual results or anticipated developments 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, which 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 applicable law, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$2,883	$3,394
Short-term investments	85,521	80,355
Receivables, net	1,529	17,144
Inventory	235	443
Prepaid expense	6,336	7,036
Total current assets	96,504	108,372
Property and equipment, net	2,436	2,121
Restricted investments	5,779	5,835
Advanced payments, non-current	1,630	—
Total assets	$106,349	$116,328
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$11,850	$6,691
Accrued expenses	11,984	19,126
Current portion of lease financing obligations	608	490
Total current liabilities	24,442	26,307
Notes payable and lease financing obligations, net	129,750	84,117
Deferred rent	8,454	8,718
Commitments and contingencies (Note 7)	—	—
Shareholders' deficit:		
Preferred stock, par value $0.01 per share, 20,000,000 shares authorized; none issued and outstanding at June 30, 2018 and December 31, 2017, respectively	—	—
Common stock, par value $0.01 per share, 150,000,000 shares authorized; 48,498,055 and 48,211,226 issued and outstanding at June 30, 2018 and December 31, 2017, respectively	485	482
Additional paid-in capital	530,336	520,072
Accumulated deficit	(587,118)	(523,368)
Total shareholders' deficit	(56,297)	(2,814)
Total liabilities and shareholders' deficit	$106,349	$116,328

See accompanying Notes to Condensed Consolidated Financial Statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue:				
Product sales, net	$1,655	$17,151	$3,244	$29,408
Costs and expenses:				
Cost of product sales	116	157	319	429
Research and development	19,412	13,137	37,551	25,377
Selling, general and administrative	12,744	15,796	23,678	28,267
Total costs and expenses	32,272	29,090	61,548	54,073
Loss from operations	(30,617)	(11,939)	(58,304)	(24,665)
Interest expense	(3,676)	(2,723)	(6,502)	(5,386)
Other income	597	303	1,056	603
Net loss	$(33,696)	$(14,359)	$(63,750)	$(29,448)
Comprehensive loss	$(33,696)	$(14,359)	$(63,750)	$(29,448)
Basic and diluted net loss per share	$(0.70)	$(0.33)	$(1.32)	$(0.67)
Weighted-average shares used to compute basic and diluted net loss per share	48,384,460	44,037,471	48,333,610	43,933,022

See accompanying Notes to Condensed Consolidated Financial Statements

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

	Six Months Ended June 30,	
	2018	2017
Operating activities:		
Net loss	$(63,750)	$(29,448)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	5,966	6,408
Non-cash interest expense	2,503	2,012
Depreciation and amortization	429	234
Changes in operating assets and liabilities:		
Receivables	15,615	(7,038)
Inventory	208	223
Prepaid expenses and other assets	(930)	(1,680)
Accounts payable, accrued expenses and other	(2,247)	8,428
Net cash used in operating activities	(42,206)	(20,861)
Investing activities:		
Purchases of property and equipment	(386)	(316)
Purchases of investments	(45,166)	(1,102)
Proceeds from the sale and maturities of investments	40,000	17,928
Net cash (used in) provided by investing activities	(5,552)	16,510
Financing activities:		
Proceeds from borrowings under notes payable	44,550	—
Proceeds upon exercise of stock options	2,877	5,637
Release of restricted investments	56	—
Payments on lease financing obligations	(236)	(124)
Net cash provided by financing activities	47,247	5,513
Net (decrease) increase in cash and cash equivalents	(511)	1,162
Cash and cash equivalents at beginning of period	3,394	2,224
Cash and cash equivalents at end of period	$2,883	$3,386
Supplemental cash flow information		
Cash paid for interest	$3,999	$3,372
Conversion of accrued interest to notes payable	$1,909	$1,628
Property acquired under capital lease	$358	$163

See accompanying Notes to Condensed Consolidated Financial Statements

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OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases and disorders of the central nervous system. Our first drug product, OMIDRIA, is marketed in the United States (U.S.) for use during cataract surgery or intraocular lens replacement.

Basis of Presentation

Our condensed consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions have been eliminated and we have determined we operate in one segment. The accompanying unaudited condensed 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 June 30, 2018 and for the three and six months ended June 30, 2018 and 2017 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2017 has been derived from our audited financial statements but does not include all of the information and footnotes required by GAAP for audited annual financial information.

The accompanying unaudited condensed consolidated financial statements and related notes thereto 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, 2017, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 1, 2018.

Going Concern

On an interim and annual basis we are required to assess our ability to continue as a going concern for one year after the date the financial statements are issued using rules defined by ASC No. 205-40 - Going Concern (the Standard). As required by the Standard, management's evaluation shall initially not take into consideration the potential mitigating effects of management's plans that have not been fully implemented as of the date the financial statements are issued. In the second step of this evaluation, management's assumptions and plans are derived according to restrictions and definitions in the Standard. As such, for purposes of this exercise, the following assumptions (which are discussed in further detail following this summary) were made:

- Limited cash receipts from sales of OMIDRIA. Even though we have received an extension of transitional pass-through reimbursement for OMIDRIA for a period of two years beginning October 1, 2018, we are unable at this time to predict accurately revenue from sales of OMIDRIA once transitional pass-through reimbursement begins. In addition, sales of OMIDRIA are generally made with 90-day collection terms and, therefore, minimal OMIDRIA cash receipts were included for this exercise prior to January 2019; and
- No public or private equity transactions or partnering revenues can be considered for purposes of this exercise in the absence of any existing or committed arrangements to raise additional capital or of any existing or consummated partnerships.

In performing the first step of the assessment, we concluded that the following conditions raise substantial doubt about our ability to meet our financial obligations as they become due. As of June 30, 2018, we had $88.4 million in cash, cash equivalents and short-term investments, $1.5 million of accounts receivable and $24.4 million in current liabilities. We have a history of net losses ($63.8 million for the six months ended June 30, 2018) and use of cash for operations ($42.2 million for the six months ended June 30, 2018). In addition, on January 1, 2018, transitional pass-through reimbursement for our only commercial product, OMIDRIA, which allowed for separate payment (i.e., outside the packaged procedural payment) under Medicare Part B expired and is not scheduled to be reinstated until October 1, 2018.

In performing the second step of this assessment, we are required to evaluate whether our plans to mitigate the conditions above alleviate the substantial doubt about our ability to meet our obligations as they become due within one year after the date the financial statements are issued. In performing this second step of the assessment, we are limited to those assumptions listed above and the restrictions and definitions in the Standard. Consequently, based on this assessment performed using the

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associated limitations required by the Standard, we have concluded there is substantial doubt about our ability to continue as a going concern through August 9, 2019.

If we are unable to raise additional equity, debt or partnering capital when needed, or upon acceptable terms, such failure would have a significant negative impact on our financial condition. Should it be necessary to manage our operating expenses, we would reduce our projected cash requirements through reduction of our expenses by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying consolidated financial statements 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 our ability to continue as a going concern.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09 (Topic 606) “Revenue from Contracts with Customers,” which requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. We adopted Topic 606 on January 1, 2018 using the modified retrospective transition method.

Once we determine that an arrangement is within the scope of Topic 606 and we believe it is probable that we will collect the consideration we are entitled to in exchange for OMIDRIA product sales, we perform the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation.

Upon adoption, we evaluated our contracts with customers and determined the adoption of the standard did not change the timing or the amounts of our previously recognized revenues.

Product Sales, Net

We generally record revenue from product sales when the product is delivered to our wholesalers. Product sales are recorded net of wholesaler distribution fees and estimated chargebacks, rebates and purchase volume discounts. Accruals or allowances are established for these deductions in the same period when revenue is recognized, and actual amounts incurred are offset against the applicable accruals or allowances. We reflect each of these accruals or allowances as either a reduction in the related account receivable or as an accrued liability, depending on how the amount is expected to be settled.

The Centers for Medicare and Medicaid Services (CMS) initially granted transitional pass-through reimbursement status for OMIDRIA through December 31, 2017. Pass-through status for OMIDRIA allowed for reimbursement payment to Ambulatory Surgery Centers (ASCs) and hospitals using OMIDRIA in procedures involving patients covered by Medicare Part B. In March 2018, the Consolidated Appropriations Act, 2018 (the Appropriations Act) was signed into law, which among other things extended pass-through reimbursement status for certain drugs, including OMIDRIA, for a two-year period beginning October 1, 2018. For the period January 1, 2018 through September 30, 2018, OMIDRIA is not subject to separate reimbursement for procedures involving patients covered by Medicare Part B.

Advanced Payments

We have various agreements with third parties that require us to pay part of the contractually due amounts in advance of receiving goods and services. These agreements relate primarily to clinical and manufacturing activities. Amounts paid in advance of services to be delivered to us beyond 12 months of the balance sheet date are recorded as non-current assets.

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, stock-based compensation expense and accruals for clinical trials, manufacturing of drug product and clinical drug supply 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.

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Recently Adopted Pronouncements

We adopted ASU 2018-05 issued by the FASB in March 2018 related to the Tax Cuts and Jobs Act (Tax Act) that was enacted in December 2017. We remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21.0%. The standard requires that we record and disclose any provisional amounts related to the Tax Act. We recorded and disclosed the provisional impact to our deferred tax balance in our Annual Report on Form 10-K for the year ended December 31, 2017 that was filed with the SEC on March 1, 2018. We are still analyzing certain aspects of the Tax Act, which could potentially affect the measurement of these assets and liabilities or potentially give rise to new deferred tax assets and liabilities.

In May 2016, the FASB issued ASU 2017-09 related to stock-based compensation, which provides guidance on the accounting for changes to the terms and conditions of stock-based payment arrangement, or modifications. We adopted the guidance January 1, 2018 and the adoption did not have a material impact on our stock-based compensation expense.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02 related to lease accounting. The new standard requires lessees to recognize a right-of-use asset and a lease liability for most leases. This standard must be applied using a modified retrospective transition method and is effective for all annual and interim periods beginning after December 15, 2018. Earlier adoption is permitted. We expect to adopt the standard on January 1, 2019 and are still in the process of evaluating the effect of adoption on our consolidated financial statements and are currently assessing our leases.

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. Common share equivalents are excluded from the diluted net loss per share computation if their effect is anti-dilutive.

The basic and diluted net loss per share amounts for the six months ended June 30, 2018 and 2017 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:

	June 30,	
	2018	2017
Outstanding options to purchase common stock	10,542,066	10,334,730
Outstanding warrants to purchase common stock	300,602	100,602
Total	10,842,668	10,435,332

Note 3—Accounts Receivable, Net

Accounts receivable, net consist of the following:

	June 30, 2018	December 31, 2017
	(In thousands)	
Trade receivables, net	$1,500	$ 17,079
Sublease and other receivables	29	65
Total accounts receivables net	$1,529	$ 17,144

Note 4—Fair-Value Measurements

As of June 30, 2018 and December 31, 2017, all investments were classified as short-term and available-for-sale on the accompanying Condensed Consolidated Balance Sheets. Investment income, which was included as a component

of other income, consists of interest earned.

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

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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 they are developed using estimates and assumptions developed by us, which reflect those that a market participant would use.
Our fair value hierarchy for our financial assets and liabilities measured at fair value on a recurring basis are as follows:

	June 30, 2018			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	$5,779	$ —	$ —	$5,779
Money-market funds classified as short-term investments	85,521	—	—	85,521
Total	$91,300	$ —	$ —	$91,300

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	$5,835	$ —	$ —	$5,835
Money-market funds classified as short-term investments	80,355	—	—	80,355
Total	$86,190	$ —	$ —	$86,190

Cash held in demand deposit accounts of $2.9 million and $3.4 million is excluded from our fair-value hierarchy disclosure as of June 30, 2018 and December 31, 2017, respectively. There were no unrealized gains or losses associated with our short-term investments as of June 30, 2018 or December 31, 2017. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets for receivables, accounts payable, other current monetary assets and liabilities and notes payable and lease financing obligations approximate fair value.

Note 5—Accrued Liabilities
Accrued liabilities consist of the following:

	June 30, 2018	December 31, 2017
	(In thousands)	
Contract research and development	$4,949	$ 4,251
Employee compensation	2,331	2,178
Consulting and professional fees	2,185	1,758
Sales rebates, fees and discounts	909	6,561
Clinical trials	546	1,026
ASC/hospital product return liability	—	2,350
Other accruals	1,064	1,002
Total accrued liabilities	$11,984	$ 19,126

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Note 6—Notes Payable and Lease Financing Obligations

Notes payable and lease financing obligations consist of the following:

	June 30, 2018	December 31, 2017
	(In thousands)	
Notes payable	$130,740	$ 83,831
Lender facility fee payable upon maturity	6,537	4,192
Lease financing obligations	1,421	1,300
Notes payable, facility fee and lease financing obligations	138,698	89,323
Unamortized debt discount	(6,827)	(3,527)
Unamortized debt issuance costs	(1,513)	(1,189)
Current portion of lease financing obligations	(608)	(490)
Non-current portion of notes payable and lease financing obligations, net	$129,750	$ 84,117

In October 2016, we entered into the CRG Loan Agreement which permits interest-only payments through December 31, 2020. Subject to the achievement of certain milestones, this interest-only period potentially could be extended through the maturity date of September 30, 2022. In November 2016, we borrowed $80.0 million under the CRG Loan Agreement and, in May 2018, we borrowed the remaining $45.0 million available to us under the CRG Loan Agreement.

The CRG Loan Agreement accrues interest at an annual rate of 12.25% (4.00% of which can be deferred at our option through December 31, 2020 by adding such amount to the aggregate principal amount). As of June 30, 2018, as allowed under the CRG Loan Agreement, we have deferred $5.7 million ($1.9 million for the six months ended June 30, 2018) of accrued interest by increasing the principal amount outstanding. The CRG Loan Agreement requires us to maintain cash and cash equivalents of $5.0 million during the term of the agreement which is recorded as restricted investments in our Condensed Consolidated Balance Sheet.

We are also required to pay a facility fee equal to 5.00% of the aggregate principal amount borrowed (including principal additions related to deferred interest) on repayment of the CRG Loan Agreement. The facility fee is being accreted to notes payable using the effective interest method over the term of the CRG Loan Agreement.

We may prepay all or a portion of the outstanding principal under the CRG Loan Agreement at any time upon prior notice subject to a prepayment fee through September 30, 2019, and with no prepayment fee being owed thereafter. In certain circumstances, including a change of control and certain asset sales or licensing transactions, we are required to prepay all or a portion of the loan, including the applicable prepayment premium on the outstanding principal to be prepaid.

After 2018, the CRG Loan Agreement requires us to achieve either (a) certain minimum net revenue amounts through the end of 2021, which is $75.0 million for the 2019 calendar year, or (b) a minimum market capitalization threshold equal to the product of 3.0 multiplied by the aggregate principal amount of loans outstanding under the CRG Loan Agreement determined as of the fifth business day following announcement of earnings results for the applicable year (i.e., $375.0 million). In the event we do not achieve either the minimum revenue amount or the minimum market capitalization threshold for a year, we can satisfy the requirement by raising additional funds through an equity or subordinated debt issuance and using the proceeds to pay down the loan balance by an amount equal to the difference between the minimum revenue amount for such year and the actual revenue amount for such year.

The CRG Loan Agreement includes customary events of default (see Note 7 of the “Notes to Consolidated Financial Statements” included in our Annual Report on Form 10-K for the year ended December 31, 2017). If there is an event of default the lenders may have the right to accelerate all our repayment obligations under the CRG Loan Agreement and to take control of our pledged assets, which consists of substantially all of our assets including our intellectual property. Under certain circumstances, a default interest rate of an additional 4.00% per annum will apply to all outstanding obligations during the existence of an event of default. There was no event of default under the CRG Loan Agreement as of June 30, 2018.

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Note 7—Commitments and Contingencies

Development Milestones and Product Royalties

We have licensed a variety of intellectual property from third parties that we are currently developing or may develop in the future. These licenses may require milestone payments during the clinical development processes as well as low single to low double-digit royalties on the net income or net sales of the product.

Contracts

We have various agreements with third parties that collectively require payment of termination fees totaling $14.2 million as of June 30, 2018 if we cancel work within specific time frames, either prior to commencing or during performance of the contracted services. This is in addition to fees associated with the CRG Loan Agreement (see Note 6).

Litigation

In May 2017, we received Notice Letters from Sandoz Inc. (Sandoz) and Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, Lupin), respectively, that Sandoz and Lupin had each filed an Abbreviated New Drug Application (ANDA) seeking approval from the Food and Drug Administration (FDA) to market a generic version of OMIDRIA prior to the expiration our patents covering OMIDRIA. In June 2017, we filed patent infringement lawsuits against Sandoz and Lupin. In May 2018, we entered into a settlement agreement and consent judgment with Lupin resolving our patent litigation against Lupin and, in July 2018, our patent infringement lawsuit against Sandoz was dismissed by stipulation of the parties based on Sandoz's revision of its Patent and Exclusivity Certification to a Paragraph III certification with respect to the patents-in-suit. As a result of an earlier settlement in October 2017 involving substantially similar assertions with Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC (collectively, Par), the Lupin settlement agreement and consent judgment and the Sandoz dismissal, all of our litigation with ANDA filers has been concluded. Based on the Par and Lupin settlement agreements and Sandoz's conversion to a Paragraph III certification, the earliest ANDA entry date for any of the three generic manufacturers is April 2032 unless otherwise subsequently authorized pursuant to the settlement agreements.

Note 8—Shareholders' Equity

Common Stock

For the six months ended June 30, 2018, we received proceeds of $2.9 million upon the exercise of stock options which resulted in the issuance of 286,829 shares of common stock. For the six months ended June 30, 2017, we received proceeds of $5.6 million upon the exercise of stock options and warrants which resulted in the issuance of 628,470 shares of common stock.

Warrants

In connection with the April 2018 amendment to the CRG Loan Agreement, we issued warrants to purchase up to 200,000 shares of our common stock with an exercise price of $23.00 per share and total fair value of $1.4 million. The warrants have a five-year term.

Note 9—Stock-Based Compensation

Stock-based compensation expense includes the amortization of stock options granted to employees and non-employees and has been reported in our Condensed Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	

Research and development	$1,185	$1,263	$2,385	$2,737
Selling, general and administrative	1,815	1,869	3,581	3,671
Total	$3,000	$3,132	$5,966	$6,408

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The fair value of each option grant to employees and directors is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were applied to employee and director stock option grants as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Estimated weighted-average fair value	$9.78	$12.25	$9.77	$8.18
Weighted-average assumptions				
Expected volatility	77 %	74 %	77 %	74 %
Expected term, in years	6.0	6.0	6.0	6.0
Risk-free interest rate	2.67 %	1.95 %	2.66 %	2.01 %
Expected dividend yield	— %	— %	— %	— %

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, 2017	9,657,259	$ 10.39		
Granted	1,574,807	14.28		
Exercised	(286,829)	10.03		
Forfeited	(403,171)	13.58		
Balance at June 30, 2018	10,542,066	$ 10.86	6.69	$ 78,273
Vested and expected to vest at June 30, 2018	10,192,265	$ 10.78	6.61	$ 76,460
Exercisable at June 30, 2018	7,303,380	$ 9.89	5.65	$ 61,035

At June 30, 2018, there were 3,238,686 unvested options outstanding that will vest over a weighted-average period of 2.84 years and 2,342,402 shares were available to grant. Excluding non-employee stock options, the total estimated compensation expense to be recognized on our unvested options is $17.2 million.

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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 condensed consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases and disorders of the central nervous system.

Our drug product OMIDRIA® is marketed in the U.S. for use during cataract surgery or intraocular lens, or IOL, replacement. In our pipeline we have clinical-stage development programs focused on: complement-associated thrombotic microangiopathies; complement-mediated glomerulonephropathies; cognitive impairment; and addictive and compulsive disorders. In addition, we have a diverse group of preclinical programs and two platforms: one capable of unlocking new G protein-coupled receptor, or GPCR, drug targets and the other used to generate antibodies. For OMIDRIA and each of our product candidates and our programs, we have retained control of all commercial rights.

Commercial Products, Product Candidates, Development Programs and Platforms

OMIDRIA. OMIDRIA is approved in the U.S. by the FDA for use during cataract surgery or IOL replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. In the U.S., OMIDRIA is sold primarily through wholesalers which, in turn, sell to ASCs and hospitals. CMS, the federal agency responsible for administering the Medicare program, granted transitional pass-through reimbursement status for OMIDRIA in 2014, effective from January 1, 2015 through December 31, 2017. As a result, payment for OMIDRIA is currently included as part of the packaged payment for the associated procedure for Medicare Part B patients. The Appropriations Act was signed into law in March 2018, which includes a provision that extends pass-through reimbursement status for a small number of drugs, including OMIDRIA, used during procedures performed on Medicare Part B fee-for-service patients for an additional two years, effective October 1, 2018 through September 30, 2020. As a result of this extension, each of these drugs, including OMIDRIA, will receive separate payment for the two-year period beginning October 1, 2018. We also continue to work through administrative means to obtain permanent separate reimbursement for OMIDRIA as well as expanding more broadly its reimbursement by Medicare Advantage and other third-party payers. OMIDRIA revenues in 2018 have been significantly reduced due to the expiration of pass-through reimbursement status and we do not expect sales of OMIDRIA to increase substantially from first quarter levels until pass-through reimbursement is reinstated in the fourth quarter of this year. For more information regarding OMIDRIA reimbursement, see "Results of Operations" and "Financial Condition - Liquidity and Capital Resources" below.

In April 2018, we announced that the results of four "real-world" clinical studies demonstrating the benefits of OMIDRIA were presented at the American Society of Cataract and Refractive Surgery and American Society of Ophthalmic Administrators Annual Meeting held in Washington, D.C. The studies examined the use of OMIDRIA in both routine and complex cataract surgery cases performed in high-volume surgery centers, with and without femtosecond laser. Also in April 2018, we announced that the Veterans Administration, or VA, added OMIDRIA to the VA National Formulary, which is a listing of drugs and supplies that must be available at all VA facilities for the benefit of U.S. military veterans.

In May 2017, we received a Notice Letter from Sandoz, Inc., or Sandoz, and a Notice Letter from Lupin Ltd. and Lupin Pharmaceuticals, Inc., which we refer to collectively as Lupin, stating that each of Sandoz and Lupin had filed with the FDA an ANDA containing a Paragraph IV Certification under the Hatch-Waxman Act seeking approval to market a generic version of OMIDRIA prior to the expiration of six Orange Book Patents. Omeros filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against each of Sandoz and Lupin in June 2017, which lawsuits were consolidated for all purposes by court order in October 2017. In May 2018, we entered into a settlement agreement and consent judgment with Lupin resolving favorably our patent litigation against Lupin. In addition, in July 2018 we announced that our patent infringement lawsuit against Sandoz had been dismissed by

stipulation of the parties based on Sandoz's conversion to Paragraph III certifications with respect to the patents covering OMIDRIA. As a result of an earlier settlement in October 2017 involving substantially similar assertions with Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC, or collectively Par, the Lupin settlement agreement and consent judgment and the Sandoz dismissal, all of our litigation with ANDA filers has been concluded. Based on the Par and Lupin settlement agreements and Sandoz's conversion to a Paragraph III certification, the earliest ANDA entry date for any of the three generic manufacturers is April 2032 unless otherwise subsequently authorized pursuant to the settlement agreements. For more information regarding these matters, see Part II, Item 1, "Legal Proceedings."

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Outside of the U.S., we have received approval from the European Commission, or EC, to market OMIDRIA in the European Economic Area, or EEA, for use during cataract surgery and other IOL replacement procedures to maintain mydriasis (pupil dilation), to prevent miosis (pupil constriction), and to reduce postoperative eye pain. In July 2018, we reported that OMIDRIA had been placed on the market in the EU on a limited basis, which maintained the ongoing validity of the European marketing authorization for OMIDRIA. Decisions about price and reimbursement for OMIDRIA are made on a country-by-country basis and may be required before marketing may occur in a particular country. Timing of any such partnerships or independent launch depends on numerous factors, including completion of mutual diligence exercises and domestic sales of OMIDRIA or entry into suitable agreements with contract service vendors, respectively. In addition, we have an exclusive supply and distribution agreement for the sale of OMIDRIA in certain countries in the Middle East, including the Kingdom of Saudi Arabia and the United Arab Emirates, under which sales began on a limited basis in the Kingdom of Saudi Arabia in 2016. We do not expect to see further sales of OMIDRIA in any countries within the EEA and other international territories if we are unable to either enter into partnerships for the marketing and distribution of OMIDRIA or complete an independent broad launch in such countries.

Product Candidates. We have the following clinical-stage programs in our pipeline:

- MASP-2 - OMS721. OMS721 is our lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2, or MASP-2, the effector enzyme of the lectin pathway of the complement system. The current development focus for OMS721 is diseases in which the lectin pathway has been shown to contribute to significant tissue injury and pathology. These diseases are typically characterized by significant end organ injuries, such as kidney or central nervous system injury, when not treated. Phase 3 clinical programs are underway for OMS721 in HSCT-TMA, in IgA nephropathy, and in atypical hemolytic uremic syndrome, or aHUS. In addition, we have two ongoing OMS721 Phase 2 clinical trials, one in patients with TMAs and the other in renal diseases currently focused on patients with IgA nephropathy. We are also developing small-molecule inhibitors of MASP-2 for oral administration that we are targeting for clinical trials in 2020.

The FDA has granted breakthrough therapy designation to OMS721 for the treatment of HSCT-TMA in patients who have persistent TMA despite modification of immunosuppressive therapy, or high-risk HSCT-TMA. We have had additional meetings recently with the FDA and with a European national regulatory authority focused on accelerated, conditional and full approval pathways for OMS721 for the treatment of HSCT-TMA. We intend to begin historical data collection later this year designed to support an accelerated approval in the U.S. and a conditional or full approval in Europe. Additional meetings with European regulators are requested and scheduled later this year. Close interactions with the FDA and European regulatory agencies are ongoing and we continue preparations for U.S. Biologics License Application, or BLA, and European Marketing Authorization Application, or MAA, submissions. We believe that we have clear paths to both accelerated and full approval of OMS721 in high-risk HSCT-TMA.

In April 2018, we reported new results in patients with HSCT-TMA from the ongoing Phase 2 study. The analysis of 100-day mortality, an important endpoint previously used as an approval endpoint in another condition related to HSCT, showed that OMS721-treated patients had improved survival relative to the historical control (53% vs 10%; p = 0.0002).

For IgA nephropathy, patient enrollment is open in our OMS721 Phase 3 clinical trial, which is referred to as ARTEMIS-IGAN, in patients at least 18 years of age with biopsy-confirmed IgA nephropathy and with 24-hour urine protein excretion greater than one gram per day at baseline on optimized renin angiotensin system, or RAS, blockade. The primary endpoint for this trial is reduction in proteinuria. This trial includes a subset of patients with baseline proteinuria levels of two or more grams per day and has been designed to include pathways for both accelerated and full approvals depending on the size and duration of the effect on proteinuria.

The Phase 3 clinical program in patients with aHUS, in which patient enrollment is ongoing, consists of one Phase 3 clinical trial – a single-arm (i.e., no control arm), open-label trial in patients with newly diagnosed or ongoing aHUS. This trial is targeting approximately 40 patients for full approval in Europe and accelerated approval in the U.S. with approximately 80 total patients required by FDA for full approval.

OMS721 has received multiple designations from the FDA and from the EMA across the three current indications. These include:

- HSCT-TMA: In the U.S., OMS721 has received from the FDA (1) breakthrough therapy designation in patients who have persistent TMA despite modification of immunosuppressive therapy and (2) orphan drug designation for the prevention (inhibition) of complement-mediated TMAs, which includes HSCT-TMA. In Europe, the EMA's Committee for Orphan Medicinal Products has issued a positive opinion for orphan designation for OMS721 for treatment in hematopoietic stem cell transplantation.

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- IgA nephropathy: In the U.S., OMS721 has received from the FDA (1) breakthrough therapy designation for the treatment of IgA nephropathy and (2) orphan drug designation in IgA nephropathy. In Europe, OMS721 has received from the EMA orphan drug designation in the treatment of primary IgA nephropathy.
- aHUS: In the U.S., OMS721 has received from the FDA (1) fast-track designation for the treatment of patients with aHUS and (2) orphan drug designation for the prevention (inhibition) of complement-mediated TMAs, which includes aHUS.
- PDE10 - OMS824. In our OMS824 program, we continue to advance our phosphodiesterase 10, or PDE10, inhibitors for treatment of neurological disorders. The FDA has approved our conducting clinical trials with our lead candidate subject to dosing limitations. Given the dosing limitations, we are currently focused on assessing the relative advantages of a number of our back-up compounds.
- PPAR - OMS405. In our peroxisome proliferator-activated receptor gamma, or PPAR , program, Phase 2 clinical trials have been conducted by our collaborators to evaluate a PPAR agonist, alone or in combination with other agents, and have yielded positive data in the treatment of addiction to heroin and to nicotine. We have also reported positive results (i.e., decreased craving and protection of brain white matter) from a Phase 2 clinical trial conducted by an independent investigator evaluating the effects of a PPAR agonist in patients with cocaine use disorder.
- PDE7 - OMS527. In our phosphodiesterase 7, or PDE7, program, we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders. A Phase 1 single-ascending- and multiple-ascending-dose clinical trial is underway and designed to assess safety and pharmacokinetics in healthy subjects. We have completed dosing in the first two cohorts of subjects. OMS527 has been well tolerated to date, and pharmacokinetic data collected to date indicate that the drug should be able to be dosed once daily. Completion of the Phase 1 trial is expected in the first half of 2019. Following Phase 1 completion, if successful, we plan to conduct our initial OMS527 Phase 2 clinical trial in patients with nicotine addiction.

Development Programs and Platforms. Our preclinical programs and platforms include:

- MASP-3 - OMS906. In our mannan-binding lectin-associated serine protease-3, or MASP-3 program, we are developing MASP-3 inhibitors for the treatment of disorders related to the alternative pathway of the complement system. In preparation for clinical trials, the manufacturing scale-up process is underway for a MASP-3 inhibitor antibody and we are currently targeting paroxysmal nocturnal hemoglobinuria, or PNH, as the first clinical indication for OMS906. We are currently planning for clinical trials to begin in late 2019 or early 2020. We are also developing small-molecule inhibitors of MASP-3.
- GPCR Platform and Programs. We have developed a proprietary cellular redistribution assay, or CRA, which we use in a high-throughput manner to identify synthetic ligands, including antagonists, agonists and inverse agonists, that bind to and affect the function of orphan GPCRs. We are conducting in vitro and in vivo preclinical efficacy studies and optimizing compounds for a number of targets including: GPR151, linked to schizophrenia and cognition; GPR161, which is associated with triple negative breast cancer and various sarcomas; GPR174, which appears to be involved in the modulation of the immune system and, in particular, increases cytokine production and inhibits production of regulatory T cells and checkpoint molecules, all of which are known to be important in cancer, in autoimmune disease, such as multiple sclerosis, and in organ transplantation; and OPN4, linked to seasonal affective disorder, mood disorders, sleep disorders and photophobia.
- Antibody Platform. Our proprietary ex vivo platform for the discovery of novel, high-affinity monoclonal antibodies, which was in-licensed from the University of Washington and then further developed by our scientists, utilizes a chicken B-cell lymphoma cell line. Using our platform and other know-how and techniques, we have generated antibodies to several clinically significant targets, including highly potent antibodies against MASP-3 and MASP-1.

Financial Summary

During the three months ended June 30, 2018 and 2017, our OMIDRIA revenues were $1.7 million and $17.2 million, respectively, and our net losses were $33.7 million and $14.4 million for the same periods. The significant reduction in OMIDRIA revenues between the periods is due to the expiration of separate Medicare reimbursement for OMIDRIA on January 1, 2018, which pursuant to the Appropriations Act will be reinstated on October 1, 2018 for a two-year-period. See “Results of Operations - Revenue” below for additional details. We expect that our net losses will continue until such time as we derive sufficient revenues from sales of OMIDRIA and/or other sources, such as

licensing, product sales and other revenues from our product candidates, to cover our expenses.

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As of June 30, 2018, we had $88.4 million in cash, cash equivalents and short-term investments available for general corporate use. In addition, we had restricted investments of $5.8 million that we were required to maintain in depository and investment accounts primarily pursuant to our Term Loan Agreement, or the CRG Loan Agreement, with CRG Servicing LLC, or CRG, as administrative and collateral agent, and the lenders identified therein, which requires us to maintain a balance of cash and cash equivalents of $5.0 million, and our lease related to the Omeros Building.

Results of Operations

Revenue

On January 1, 2018, we adopted Accounting Standards Update (ASU) 2014-09 (Topic 606) “Revenue from Contracts with Customers” using the modified retrospective transition method. The adoption of ASU 2014-09 did not change the timing or the amounts of our previously recognized revenue. For more information regarding revenue recognition, see Part I, Item 1, Note 1 - “Organization and Significant Accounting Policies.”

Our revenue consists of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Product sales, net	$1,655	$17,151	$3,244	$29,408

CMS granted transitional pass-through reimbursement status for OMIDRIA through December 31, 2017. Pass-through status for OMIDRIA allowed for separate reimbursement payment (i.e., outside the packaged procedural payment) to ASCs and hospitals using OMIDRIA in procedures involving patients covered by Medicare Part B. In March 2018, the Appropriations Act was signed into law, which among other things extended pass-through reimbursement status for certain drugs, including OMIDRIA, for a two-year period beginning October 1, 2018. For the period January 1, 2018 through September 30, 2018, OMIDRIA is not subject to pass-through reimbursement payment for procedures involving patients covered by Medicare Part B and, therefore, is not subject to separate reimbursement for procedures involving these patients.

During the three and six months ended June 30, 2018, OMIDRIA revenue was $1.7 million and $3.2 million as compared to $17.2 million and $29.4 million for the three and six months ended June 30, 2017. The decrease in revenue during the three and six months ended June 30, 2018 compared to the same periods in prior year was due to the significantly reduced usage of OMIDRIA by ASCs and hospitals following the expiration of transitional pass-through reimbursement status for OMIDRIA on January 1, 2018.

We expect product sales, net to increase in the third quarter of 2018 from the first and second quarter because we expect to be able to recognize revenue related to re-establishing wholesaler inventories in anticipation of the October 1, 2018 reinstatement of OMIDRIA pass-through reimbursement. We expect product sales, net to increase significantly in the fourth quarter as compared to the first three quarters of 2018 as ASCs and hospitals recommence their use of OMIDRIA. We cannot predict how quickly or the extent to which ASCs and hospitals will resume or increase their usage of OMIDRIA. In addition, we are continuing to pursue administrative means to obtain permanent separate payment or similar reimbursement for OMIDRIA beyond September 30, 2020, but can provide no assurance that these efforts will be successful.

Gross-to-Net Deductions

We record OMIDRIA product sales net of estimated chargebacks, rebates, distribution fees and product returns. These deductions are generally referred to as gross-to-net deductions. Our total gross-to-net provision for the three and six months ended June 30, 2018 was 20.4% and 24.8%, respectively of gross OMIDRIA product sales. This compares to 25.4% and 23.8% for the corresponding periods in 2017. The primary reason for the lower gross-to-net deductions in 2018 is the reduction in rebates related to our volume discount program with ASCs.

A summary of our gross-to-net related accruals for the six months ended June 30, 2018 is as follows:

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	Chargebacks and Rebates	Distribution Fees and Product Return Allowances	Total
	(In thousands)		
Balance as of December 31, 2017	$5,724	$ 3,373	$9,097
Provisions	782	288	1,070
Payments	(6,290)	(2,827)	(9,117)
Balance as of June 30, 2018	$216	$ 834	$1,050

Chargebacks and Rebates

We record a provision for estimated chargebacks and rebates at the time we recognize OMIDRIA product sales revenue and reduce the accrual when payments are made or credits are granted. Our chargebacks are related to a Pharmaceutical Pricing Agreement, a Federal Supply Schedule agreement, a 340B prime vendor agreement and a Medicaid Drug Rebate Agreement. We also record a provision for estimated rebates for our OMIDRIAssure Reimbursement Services Program and our purchase volume discount programs.

We expect that when sales increase following reinstatement of pass-through on October 1, 2018, our provision for chargebacks and rebates as a percentage of gross sales will be comparable to our historical norms prior to December 31, 2017.

Distribution Fees and Product Return Allowances

We pay our wholesalers a distribution fee for services they perform for us based on the dollar value of their purchases of OMIDRIA. We record a provision for these charges as a reduction to revenue at the time of sale to the wholesaler and make payments to our wholesalers based on contractual terms.

We allow for the return of product up to 12 months past its expiration date or for product that is damaged or not used by our customers. We record a provision for returns upon sale of OMIDRIA to our wholesaler. When a return or claim is received, we issue a credit memo to the wholesaler against its outstanding receivable to us or reimburse the customer.

We expect that when sales increase following reinstatement of pass-through on October 1, 2018, our provision for distribution fees and product return allowances as a percentage of gross sales will be comparable to our historical norms prior to December 31, 2017.

Research and Development Expenses

Our research and development expenses can be divided into three categories: 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. Direct external expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations, contract research organizations, or CROs, clinical trial sites, collaborators, licensors and consultants and lab supplies. 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. We do not generally allocate our internal resources, employees and infrastructure to any individual research project because we deploy them across multiple clinical and preclinical projects that we are advancing in parallel.

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The following table illustrates our expenses associated with these activities:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Direct external expenses:				
Clinical research and development:				
MASP-2 Program - OMS721	$8,315	$3,605	$16,243	$7,455
OMIDRIA - Ophthalmology	675	1,377	1,284	2,412
Other clinical programs	450	34	662	89
Total clinical research and development	9,440	5,016	18,189	9,956
Preclinical research and development	2,807	903	4,438	1,573
Total direct external expenses	12,247	5,919	22,627	11,529
Internal, overhead and other expenses	5,980	5,955	12,539	11,111
Stock-based compensation expense	1,185	1,263	2,385	2,737
Total research and development expenses	$19,412	$13,137	$37,551	$25,377

The $6.3 million and $11.1 million increase in direct external expenses for the three and six months ended June 30, 2018, compared to the same periods in 2017 was due primarily to higher third-party manufacturing scale-up costs for our OMS721 program as we continue to increase our production capacity to meet anticipated clinical and commercial requirements and incremental clinical costs associated with initiating our OMS721 IgA nephropathy Phase 3 clinical trial. In addition, higher third-party development expenses were incurred as we continue to advance toward the clinic our preclinical product candidates including OMS527 and small-molecule inhibitors in our MASP-2 program. These increases were partially offset by decreased costs due to completing the transfer of OMIDRIA manufacturing to a new facility in December 2017.

The changes in internal, overhead and other expenses are primarily due to increased employee related costs.

For the remainder of 2018, we expect the majority of our research and development expenses will be related to OMS721 with lesser contributions from our OMS527, OMS906, and GPCR programs. We expect our overall research and development costs to continue to increase for the remainder of 2018 given our ongoing Phase 3 clinical programs, the initiation of the Phase 1 OMS527 trial in July 2018, and our increased manufacturing efforts.

At this time, we are unable to estimate with any certainty the longer-term costs we will incur in the continued development of our product candidates due to the inherently unpredictable nature of our preclinical and clinical development activities. Clinical development timelines, the probability of success and development costs can differ materially as new data become available and as expectations change. While we are focused currently on advancing our product development programs, our future research and development expenses will depend, in part, on the preclinical or clinical success of each product candidate as well as ongoing assessments of each program’s commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates, if any, 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 are required to expend substantial resources in the development of our product candidates due to the lengthy process of completing clinical trials and seeking regulatory approval. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could delay our generation of product revenue and increase our research and development expenses and, in turn, could have a material adverse effect on our operations, financial condition and liquidity. Because of the factors above, we are not able to estimate with any certainty when or if we would recognize any net cash inflows from our research and development projects.

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Selling, General and Administrative Expenses

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Selling, general and administrative expenses, excluding stock-based compensation expense	$10,929	$13,927	$20,097	$24,596
Stock-based compensation expense	1,815	1,869	3,581	3,671
Total selling, general and administrative expenses	$12,744	$15,796	$23,678	$28,267

The decrease in selling, general and administrative expenses during the three and six months ended June 30, 2018 compared to the same periods in 2017 was primarily due to decreased legal costs associated with the conclusion of our patent infringement lawsuit against Par, which was resolved in October 2017.

We expect that our selling, general and administrative expenses for the remainder of 2018 will increase from current levels due to the expansion of OMIDRIA field sales force and increased marketing activities associated with the October 1, 2018 reinstatement of OMIDRIA pass-through status. In addition, pre-commercialization activities associated with OMS721 will add to our overall costs when compared to the first two quarters of this year.

Interest Expense

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Interest expense	$3,676	$2,723	$6,502	$5,386

The increase in interest expense during the three and six months ended June 30, 2018 compared to the same periods in the prior year was primarily due to the May 2018 borrowing of the remaining $45.0 million available to us under the CRG Loan Agreement and deferred interest being added to the outstanding balance under our CRG Loan Agreement.

Financial Condition - Liquidity and Capital Resources

We have historically generated net losses and incurred negative cash flows from operations ($33.7 million and $42.2 million, respectively, for the six months ended June 30, 2018). As of June 30, 2018, we had $88.4 million in cash, cash equivalents and short-term investments available for general corporate use that are held principally in money-market accounts as compared to $83.7 million at December 31, 2017. Our accounts receivable balance at June 30, 2018 was $1.5 million compared to $17.1 million at December 31, 2017 due to significantly reduced 2018 revenues for OMIDRIA because of the temporary loss of pass-through reimbursement effective January 1, 2018, as discussed below. We also had $24.4 million of current liabilities outstanding at June 30, 2018 compared to $26.3 million as of December 31, 2017.

Our notes payable and lease financing obligation increased to $130.4 million as of June 30, 2018, compared to $84.6 million as of December 31, 2017, primarily due to the borrowing of the remaining $45.0 million available to us under our CRG Loan Agreement and the deferral of $1.9 million of interest payments also under our CRG Loan Agreement. For more information regarding the CRG Loan Agreement, see Part I, Item 1, Note 6 - “Notes Payable and Lease Financing Obligations.”

As described earlier in this section under “Results of Operations - Revenue” CMS granted transitional pass-through reimbursement status for OMIDRIA through December 31, 2017. In March 2018, the Appropriations Act was signed into law, which among other things extended pass-through reimbursement status for certain drugs, including OMIDRIA, for a two-year period beginning October 1, 2018.

We expect the significantly reduced OMIDRIA demand to continue until reimbursement status of OMIDRIA is reinstated on October 1, 2018 as a substantial majority of facilities that were previously using OMIDRIA have suspended use or are using it on a selective basis only. This significant reduction in OMIDRIA usage will have a negative impact on our cash flows for the majority of 2018 as sales for OMIDRIA are not expected to increase substantially from the first quarter until pass-through reimbursement is reinstated and we collect the receivables associated with the increase in OMIDRIA sales to our wholesalers. Once reimbursement payment is reinstated, we anticipate OMIDRIA revenues will increase but we cannot predict how quickly or the extent to which ASCs and hospitals will resume or increase their usage of OMIDRIA.

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We expect to continue to incur negative cash flows until OMIDRIA product sales or other sources of revenue (e.g., corporate partnering, licensing or product sales) generate sufficient cash inflows to finance our operations and debt service requirements. Until we are cash-flow positive, we will need to continue to raise operating funds through the issuance of public or private equity securities, incurring additional debt and/or pursuing partnering and licensing opportunities.

On an interim and annual basis we are required to assess our ability to continue as a going concern for one year after the date the financial statements are issued using rules defined by ASC No. 205-40 - Going Concern, or the Standard. In performing the assessment, we are required to evaluate whether our plans to mitigate the conditions above alleviate the substantial doubt about our ability to meet our obligations as they become due within one year after the date the financial statements are issued. In performing this assessment, we are limited to the restrictions and definitions in the Standard. As such, we did not consider any future sources of working capital that we may otherwise be able to access. Consequently, based on the assessment we performed using the associated limitations required by the Standard, we have concluded that there is substantial doubt about our ability to continue as a going concern through August 9, 2019.

Cash Flow Data

	Six Months Ended June 30,	
	2018	2017
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	$(42,206)	$(20,861)
Investing activities	(5,552)	16,510
Financing activities	47,247	5,513

Operating Activities. Net cash used in operating activities for the six months ended June 30, 2018 increased by $21.3 million as compared to the same period in 2017. The increase in cash used in operating activities in the current period compared to the prior year largely resulted from an increase in our net loss of $34.3 million and a $10.7 million decrease in funds provided by accounts payable, accrued expenses and other. This increase in cash used in operating activities was partially offset by a $22.7 million increase in funds provided due to the collection of accounts receivable that existed as of December 31, 2017. The accounts receivable were not replaced in the current year due to significantly reduced revenue related to the temporary loss of pass-through reimbursement for OMIDRIA.

Investing Activities. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and proceeds from the sale of short-term investments, thus causing a shift between our cash and cash equivalents and short-term investment balances. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider these fluctuations in cash flows to be important to the understanding of our liquidity and capital resources.

Net cash used in investing activities during the six months ended June 30, 2018 was $5.6 million, a change of $22.1 million from the $16.5 million in net cash provided from investing activities for the same period in 2017. The primary differences between the periods is that in the six months ended June 30, 2018, we used the $44.6 million we received under the CRG Loan Agreement in May 2018 to purchase investments. In addition, investments sold increased by $22.1 million during the six months ended June 30, 2018 compared to the same period in 2017 in order to provide cash to fund our operations due to the increase in our net loss.

Financing Activities. Net cash provided by financing activities during the six months ended June 30, 2018 was $47.2 million, an increase of $41.7 million compared to the same period in 2017. The increase in net cash provided by financing activities for the six months ended June 30, 2018 included the $44.6 million incremental borrowing in May 2018 under our CRG loan agreement.

Loan and Security Agreement

In October 2016, we entered into the CRG Loan Agreement, pursuant to which we pledged substantially all of our assets, including intellectual property, as collateral. In May 2018, we borrowed the remaining $45.0 million available under the CRG Loan Agreement, and as of June 30, 2018, $130.7 million was outstanding. For more information

regarding the CRG Loan Agreement, see Part I, Item 1, Note 6 - “Notes Payable and Lease Financing Obligations.”

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Contractual Obligations and Commitments

Our future minimum contractual commitments and obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2017 that was filed with the SEC on March 1, 2018. Other than the following, our future minimum contractual obligations and commitments have not changed materially from the amounts previously reported.

Goods & Services

We have certain non-cancelable obligations under various other agreements for the acquisitions of goods and services associated with the manufacturing of our product candidates that contain firm commitments. As of June 30, 2018, our aggregate firm commitments are $14.2 million.

We may also be required, in connection with in-licensing or asset acquisition agreements, to make certain royalty and milestone payments and we cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. Therefore, such payments are not included in the amount above.

Critical Accounting Policies and Significant Judgments and Estimates

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

We believe the judgments, estimates and assumptions associated with the following critical accounting policies have the greatest potential impact on our condensed consolidated financial statements:

- Revenue recognition;
- Research and development expenses, primarily clinical trial expenses and manufacturing of drug product and clinical drug supply; and
- Stock-based compensation.

For a detailed discussion of these critical accounting policies and significant judgments and estimates, refer to "Critical Accounting Policies and Significant Judgments and Estimates" within "Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2017 that was filed with the SEC on March 1, 2018. There have not been any material changes in our critical accounting policies and significant judgments and estimates as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

Off-Balance Sheet Arrangements

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

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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 high-credit-quality securities. As of June 30, 2018, we had cash, cash equivalents and short-term investments of $88.4 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These securities in our investment portfolio are not leveraged and are classified as available-for-sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates and, with our current portfolio of short-term investments, we are not exposed to potential loss due to changes in interest rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of June 30, 2018. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2018, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

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PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In May 2017, we received Notice Letters from Sandoz and Lupin that each had filed an ANDA containing a Paragraph IV Certification under the Hatch-Waxman Act seeking approval from the FDA to market a generic version of OMIDRIA prior to the expiration of six Orange Book-listed patents covering OMIDRIA. On June 21, 2017, we filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Sandoz and on June 22, 2017 we filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Lupin. The Delaware lawsuits against Sandoz and Lupin were consolidated for all purposes by court order entered on October 16, 2017. The lawsuits were filed under the Hatch-Waxman Act for Sandoz's and Lupin's respective infringement of six Omeros patents: U.S. Patent Nos. 8,173,707, 8,586,633, 9,066,856, 9,278,101, 9,399,040 and 9,486,406, which relate to OMIDRIA and are listed in the Orange Book. A seventh patent related to OMIDRIA, U.S. Patent 9,855,246, was issued to Omeros on January 2, 2018, was then listed in the Orange Book for OMIDRIA on January 9, 2018, and both lawsuits were subsequently amended to assert this additional patent.

On May 22, 2018, we entered into a settlement agreement and consent judgment with Lupin resolving our patent litigation against Lupin. Pursuant to the Lupin settlement agreement, Lupin acknowledged and confirmed the validity of each of the Orange Book-listed patents for OMIDRIA. Under the terms of the Lupin settlement agreement, the parties executed a consent judgment that was filed with the U.S. District Court for the District of Delaware on May 23, 2018. We previously entered into a settlement agreement with Par, under which Par is precluded from launching a generic version of OMIDRIA until April 1, 2032 unless subsequently authorized pursuant to terms in that settlement agreement. In accordance with the Lupin settlement agreement and consent judgment with Lupin, Lupin is prohibited by the judgment from launching a generic version of OMIDRIA until the earlier of (1) April 1, 2032 if Par has forfeited its six month first-ANDA filer exclusivity, (2) October 1, 2032 if Par has not forfeited its six month first-ANDA filer exclusivity, or (3) a date on which we or a third party, through licensing of, any future final legal judgment regarding, or the delisting, abandonment or expiration of our U.S. OMIDRIA patents, is able to launch a generic version of OMIDRIA. Under the Lupin settlement agreement, Lupin has been granted a non-exclusive, non-sublicensable license to make, sell and distribute a generic version of OMIDRIA between the permitted launch date and the latest expiration of our U.S. patents related to OMIDRIA (i.e., at least October 23, 2033) and a non-exclusive, non-sublicensable waiver of our pediatric exclusivity for OMIDRIA until at least April 23, 2034. During these license and exclusivity waiver periods, unless Par has not forfeited its six month first-ANDA filer exclusivity and until we or a third party launches a generic version of OMIDRIA, Lupin is required to pay us a royalty equal to 15% of Lupin's net sales of its generic version of OMIDRIA until our U.S. patents related to OMIDRIA expire, and thereafter an exclusivity waiver fee of 15% of Lupin's net sales of its generic version of OMIDRIA until our pediatric exclusivity for OMIDRIA expires.

On July 24, 2018, following Sandoz's amendment of its ANDA to revise its Patent and Exclusivity Certification from a Paragraph IV certification to a Paragraph III certification, we and Sandoz filed in the U.S. District Court for the District of Delaware a stipulation to dismiss without prejudice our lawsuit against Sandoz. Sandoz's amendment of its ANDA to include a Paragraph III certification means that the FDA cannot approve the ANDA until after the July 2033 expiry of the Orange Book-listed patents. In the stipulated dismissal, which was entered by the court on July 25, 2018, Sandoz stipulated and agreed that it was no longer seeking approval of its ANDA until after the expiration of the patents that have been listed in the Orange Book for OMIDRIA.

As a result of the Par settlement agreement, the Lupin settlement agreement and consent judgment and the Sandoz dismissal, all of our litigation with ANDA filers has been concluded. Based on these outcomes, the earliest ANDA entry date for any of the three generic manufacturers is April 2032 unless otherwise subsequently authorized pursuant to the settlement agreements.

ITEM 1A. RISK FACTORS

The risks and uncertainties described below may have a material adverse effect on our business, prospects, financial condition or operating results. In addition, we may be adversely affected by risks that we currently deem immaterial or

by other risks that are not currently known to us. You should carefully consider these risks before making an investment decision. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2017.

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Risks Related to Our Products, Programs and Operations

Our ability to achieve profitability is dependent on the commercial success of OMIDRIA. To the extent OMIDRIA is not successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

OMIDRIA is our only product that has been approved by the FDA for commercial sale in the U.S. For the three months ended June 30, 2018, we recorded net sales of OMIDRIA of $1.7 million. We have not generated revenue from sales of OMIDRIA to date that is sufficient to fund fully our operations and cannot provide assurance that we will generate sufficient revenue from OMIDRIA in the future to fund fully our operations. We will need to generate substantially more product revenue from OMIDRIA to achieve and sustain profitability. Our ability to generate significant revenue from OMIDRIA product sales depends on our ability to achieve increased market acceptance of, and to otherwise market and sell effectively, OMIDRIA, which may not occur for a number of reasons, including:

- pricing, coverage and reimbursement policies of government and private payers such as Medicare, Medicaid, the VA, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- a lack of acceptance by physicians, patients and other members of the healthcare community;
- the availability, relative price and efficacy of the product as compared to alternative treatment options or branded, compounded or generic competing products;
- an unknown safety risk;
- the failure to enter into and maintain acceptable partnering arrangements for marketing and distribution of OMIDRIA outside of the U.S.;
- changed or increased regulatory restrictions in the U.S., EU and/or other foreign territories; and
- a lack of adequate financial or other resources.

The scheduled expiration of pass-through reimbursement status for OMIDRIA under Medicare Part B effective January 1, 2018 has adversely affected our revenues, and we cannot predict when or to what extent significant growth in OMIDRIA sales will occur in the future.

Effective January 1, 2018, as scheduled, OMIDRIA no longer has separate payment under Medicare Part B. Consequently, ASCs and hospitals receive from CMS the same procedural payment whether or not OMIDRIA is used for the procedure. Due to the scheduled transitional pass-through expiration, we saw a significant reduction in ASC and hospital demand for OMIDRIA beginning in December 2017 and a corresponding decrease in sales to our wholesalers that has continued into 2018. Although pass-through reimbursement status for OMIDRIA is scheduled to resume on October 1, 2018 for a two-year period, we cannot predict how quickly ASCs or hospitals will resume or increase their usage of OMIDRIA once this period begins. OMIDRIA sales to date in 2018 have been substantially reduced, which we expect will continue prior to the October 1, 2018 effective date. Some ASCs and/or hospitals that used OMIDRIA prior to the transitional pass-through expiration could decide not to resume using OMIDRIA after October 1, 2018, which would inhibit or limit our potential sales growth.

We continue to work through administrative means to obtain permanent separate or similar reimbursement for OMIDRIA. However, this requires action from administrative authorities and, consequently, we cannot guarantee that any such action will be taken or, if taken, when such action will be effective, nor can we predict the actual reimbursement rate. In addition, we cannot guarantee that Medicare Part B separate payment, or an extension of pass-through reimbursement status, will be available after September 30, 2020.

Any of these risks, if realized, would adversely affect our ability to generate revenue and attain profitability and there could be a material adverse effect on our financial condition, results of operations and growth prospects and the trading price of our stock could decline.

If OMIDRIA or any other product that we develop and commercialize does not receive adequate coverage or reimbursement from governments or private payers, or if we do not establish and maintain market-acceptable pricing for OMIDRIA or those potential other commercialized products, our prospects for revenue and profitability would suffer.

Our revenues and profitability will depend heavily on the pricing, availability and duration of adequate coverage or reimbursement for the use of products that we or our third-party business partners commercialize, including

OMIDRIA, from government, private and other third-party payers, both in the U.S. and in other countries. Any product that we bring to market may not be considered cost-effective and/or the amount reimbursed for any product may be insufficient to allow us to sell the

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product profitably. Obtaining coverage and reimbursement for any product from each government or third-party payer can be a time-consuming and costly process that may require expansion of staff and/or increased use of third parties and could require us to provide additional supporting scientific, clinical and cost-effectiveness data for the use of our approved products to each payer. We can provide no assurances at this time regarding the cost-effectiveness of OMIDRIA or any of our product candidates. Further, we can provide no assurance that the amounts, if any, reimbursed to surgical facilities for utilization of any of our surgery-related products, including OMIDRIA or any of our product candidates, or to surgeons for the administration and delivery of these products or product candidates will be considered adequate to justify the use of these products or product candidates. In addition, obtaining acceptable coverage and reimbursement from one payer does not guarantee that we will obtain similar acceptable coverage or reimbursement from another payer.

There may be significant delays in obtaining coverage or reimbursement for newly approved products, and we may not be able to provide data sufficient to be granted coverage or reimbursement. Even when a payer determines that a product is eligible for reimbursement, coverage may be limited to the uses of a product that are either approved by the FDA (or, in other countries, the relevant country's regulatory agency) and/or appear in a recognized drug compendium, and other conditions may apply. Moreover, eligibility for coverage does not mean that any product will be reimbursed at a rate that allows us to make a profit in all cases or at a rate that covers our costs, including research, development, manufacturing, sales and distribution. Increasingly, government and private third-party payers that reimburse for healthcare services and products are requiring that companies provide them with predetermined discounts from list prices and challenging the prices charged for medical products, which could adversely impact the pricing of our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. Pricing may also be adversely affected by changes in the terms, scope and/or complexity of government pricing requirements. Even if we achieve coverage or reimbursement for a product, the initial rate or method at which the product will be reimbursed could become unfavorable to us at the time reimbursement is initiated or in the future or may be of a limited duration.

In non-U.S. jurisdictions, we must obtain separate reimbursement approvals and comply with related foreign legal and regulatory requirements. In some countries, including those in the EU, our products may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time and expenditure of resources after the receipt of marketing approval for a product. We provide no assurances that the price of any product in one or more of these countries or regions will allow us to make a profit or cover our costs, including research, development, manufacturing, sales and distribution, and as a result we may decide to delay, potentially indefinitely, initiating sales in the particular country or region.

If the reimbursement or pricing that we are able to obtain and maintain for any product that we develop and commercialize, including OMIDRIA, is inadequate, is significantly delayed or is subject to overly restrictive conditions, our ability to generate revenue, attain profitability and/or commercialize our product candidates may be impaired and there could be a material adverse effect on our business, financial condition, results of operations and growth prospects and the trading price of our stock could decline.

Our operating results are unpredictable and may fluctuate.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- the level and timing of commercial sales of OMIDRIA, as well as our product candidates if and when approved or commercialized;
- the extent of coverage and reimbursement for OMIDRIA;
- the amount of OMIDRIA chargebacks, rebates and product returns;
- the extent of any payments received from collaboration arrangements and development funding as well as the achievement of development and clinical milestones under collaboration and license agreements that we may enter into from time to time and that may vary significantly from quarter to quarter; and
- the timing, cost and level of investment in our research and development activities as well as expenditures we will or may incur to acquire or develop additional technologies, products and product candidates.

In addition, the number of procedures in which OMIDRIA or any of our product candidates, if commercialized, would be used may be significantly less than the total number of such procedures performed or total possible market size. These and other factors, including our limited history of product sales, may make it difficult for us to forecast and provide accurate guidance (including updates to prior guidance) related to our expected financial performance. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

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We have incurred cumulative operating losses since inception. If we are unable to raise additional capital when needed, our commercial operations may be limited and we may be unable to complete the development and commercialization of our product candidates or to continue our other preclinical development programs.

Our operations have consumed substantial amounts of cash since our incorporation and, as of June 30, 2018, we had an accumulated deficit of approximately $587.1 million. We expect to continue to spend substantial amounts to:

- initiate and conduct clinical trials for our programs and product candidates;
- continue OMIDRIA sales and marketing;
- continue research and development in our programs;
- make principal, interest and fee payments under the CRG Loan Agreement; and
- commercialize and launch product candidates for which we may receive regulatory approval.

We expect to continue to incur additional losses until such time as we generate significant revenue from the sale of OMIDRIA, other commercial products and/or partnering. We are unable to predict the extent of any future losses and cannot provide assurance that we will generate sufficient revenue from OMIDRIA or other commercial products in the future to fund fully our operations. To date we have not generated revenue from sales of OMIDRIA that is sufficient to fund fully our operations. If we are unable to generate sufficient revenue from the sale of OMIDRIA, other commercialized products and/or partnering arrangements, we may never become and remain profitable and will be required to raise additional capital to continue to fund our operations. We cannot be certain that additional capital will be available to us on acceptable terms, if at all, when required. Adverse developments to our financial condition or business, as well as disruptions in the global equity and credit markets, may limit our ability to access capital. If we do not raise additional capital when needed through one or more funding avenues, such as corporate partnering or debt or equity financings, 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 preclinical programs or other research and development initiatives. In addition, we may be required to seek collaborators for one or more of our current or future products at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might be available or to relinquish or license on unfavorable terms our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves. We also may have insufficient funds or otherwise be unable to advance our preclinical programs, such as potential new drug targets developed from our GPCR program, to a point where they can generate revenue through partnerships, collaborations or other arrangements. Any of these actions could limit the amount of revenue we are able to generate and harm our business and prospects.

Management, as well as our independent registered public accounting firm, have concluded that a substantial doubt is deemed to exist concerning our ability to continue as a going concern.

Accounting Standards Update, or ASU, 2014-15, requires management to assess our ability to continue as a going concern for one year after the date the financial statements are issued. As further discussed in Part I, Item 1, Note 1 “Organization and Significant Accounting Policies-Going Concern” to our Consolidated Financial Statements in this Quarterly Report on Form 10-Q, substantial doubt is deemed to exist about the company’s ability to continue as a going concern through August 9, 2019. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern will require us to generate positive cash flow from operations, obtain additional financing, enter into strategic alliances and/or sell assets. The reaction of investors to the inclusion of a going concern statement in this Quarterly Report on Form 10-Q, our current lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into strategic alliances and/or make our scheduled debt payments on a timely basis or at all. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

We are subject to extensive government regulation and the failure to comply with these regulations may have a material adverse effect on our operations and business.

Both before and after approval of any product, we and our suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the U.S. and other countries, covering, among other things, testing, manufacturing, quality control, clinical trials, post-marketing studies, risk management plans, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions: warning letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and

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other monetary penalties; adverse publicity; and disruptions to our business. Further, government investigations into potential violations of these laws would require us to expend considerable resources and face adverse publicity and the potential disruption of our business even if we are ultimately found not to have committed a violation.

Obtaining FDA approval of our product candidates 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 any of our product candidates on a timely basis, if at all. Even if we discuss with, and obtain feedback from, the FDA regarding our proposed clinical trials and nonclinical studies before initiating those trials or studies, the FDA may decide that the design of our clinical trials as actually run or our resulting data are insufficient for approval of our product candidates and require additional preclinical, clinical or other studies or additional work related to chemistry, manufacturing and controls. In addition, we, the FDA or an independent institutional review board or ethics committee may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are or would be exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials. If we are required to conduct additional trials or to conduct other testing of our product candidates beyond that which we currently contemplate for regulatory approval, if we are unable to complete successfully 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 face substantial additional expenses, be delayed in obtaining marketing approval for our product candidates or may never obtain marketing approval.

We are also required to comply with extensive governmental regulatory requirements after a product has received marketing authorization. Governing regulatory authorities may require post-marketing studies that may negatively impact the commercial viability of a product. Once on the market, a product may become associated with previously undetected adverse effects and/or may develop manufacturing difficulties. We are required to comply with other post-marketing requirements including Good Manufacturing Practices, advertising and promotion restrictions, pharmacovigilance requirements including risk management activities, reporting and recordkeeping obligations and other requirements. As a result of any of these requirements or other problems, a product's regulatory approval could be withdrawn, which could harm our business and operating results. In addition, we must establish and maintain an effective healthcare compliance program in order to comply with U.S. and other laws applicable to marketed drug products and, in particular, laws (such as the Anti-Kickback Statute, the False Claims Act and the Sunshine Act) applicable when drug products are purchased or reimbursed by a federal healthcare program. U.S. laws such as the Foreign Corrupt Practices Act prohibit the offering or payment of bribes or inducements to foreign public officials, including potentially physicians or other medical professionals who are employees of public health care entities. In addition, many countries have their own laws similar to the healthcare compliance laws that exist in the U.S. Implementing and maintaining an effective compliance program requires the expenditure of significant time and resources. If we are found to be in violation of any of these laws, we may be subject to significant penalties, including but not limited to civil or criminal penalties, damages and fines as well as exclusion from government healthcare programs.

We may face difficulties from changes to current regulations as well as future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

There is uncertainty with respect to the impact that health care reform legislation may have on coverage and reimbursement for healthcare items and services covered by plans that are authorized by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA. President Trump and various members of Congress have expressed a desire to repeal all or portions of the ACA and in December 2017 portions of the ACA dealing with the individual mandate insurance requirement were effectively repealed by the Tax Cuts and Jobs Act of 2017, or the 2017 Tax Act. In addition, other legislative changes have been

proposed and adopted since the ACA was enacted. President Trump and the Secretary of Health and Human Services have also made statements about controlling drug prices. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or executive order or the impact that the resulting changes may have on us.

We expect that the ACA, if it remains in effect, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and, in addition, downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate sufficient revenue, attain and/or maintain profitability or commercialize our product candidates. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or

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interpretations will be changed, or what the impact of such changes on OMIDRIA or the marketing approvals of our product candidates, if any, may be.

U.S. federal income tax reform could adversely affect us.

The 2017 Tax Act, among other things, includes changes to U.S. federal tax rates, imposes additional limitations on the deductibility of interest, changes to the Orphan Drug Credit, allows for the expensing of capital expenditures, puts into effect the migration from a "worldwide" system of taxation to a territorial system and modifies or repeals many business deductions and credits. The estimated impact of the 2017 Tax Act is based on our management's current knowledge and assumptions and recognized impacts could be materially different from current estimates based on further analysis of the new law. For the year ended December 31, 2017, we revalued our net deferred tax assets and liabilities at the newly enacted U.S. corporate rate, and the estimated impact was recognized in our financial statements for the year ended December 31, 2017. We are still analyzing certain aspects of the 2017 Tax Act, which could potentially affect the measurement of our deferred tax assets and liabilities or potentially give rise to new deferred tax assets and liabilities.

Failure to obtain and maintain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.

We intend to have OMIDRIA and our product candidates, if approved, marketed outside the U.S. In order to market our products in non-U.S. jurisdictions, we or our partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The regulatory approval procedure varies among countries and can involve additional testing and data review. The requirements governing marketing authorization, the conduct of clinical trials, pricing and reimbursement vary from country to country. Approval by the FDA or the EMA does not ensure approval by regulatory agencies in other jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. The time required to obtain regulatory approval outside the U.S. and EU may differ from that required to obtain FDA or EMA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these "Risk Factors" and we may not obtain foreign regulatory approvals on a timely basis, or at all. In addition, even if we were able to obtain regulatory approval for a product in one or more foreign jurisdictions, we may need to complete additional requirements to maintain that approval and our ability to market the product in the applicable jurisdiction.

OMIDRIA, as well as any of our product candidates, if approved, that are marketed outside of the United States, may face a variety of risks associated with international operations that, if realized, could materially adversely affect our business.

We may be subject to additional risks for OMIDRIA or any of our product candidates that are marketed outside the U.S., including:

- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign currency fluctuations and other obligations incident to doing business in another country; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

Any of these risks, if realized, could increase our operating expenses and reduce our revenues.

We have no internal capacity to manufacture commercial or clinical supplies of OMIDRIA or our product candidates and intend to rely solely on third-party manufacturers. If the contract manufacturers that we rely on experience difficulties manufacturing and supplying OMIDRIA or our product candidates or fail FDA or other regulatory inspections, our clinical trials, regulatory submissions and ability to sell OMIDRIA or any other commercialized product and generate revenue may be significantly limited or delayed.

We rely and intend to continue to rely on third-party manufacturers to produce commercial quantities of OMIDRIA and clinical drug supplies of our product candidates that are needed for clinical trials. We cannot provide any assurance that we will be able to enter into or maintain these types of arrangements on commercially reasonable terms, or at all. If we or the manufacturer were to terminate one of these arrangements early, or the manufacturer was unable

to supply product quantities sufficient to meet our requirements, we would be required to transfer the manufacturing to an approved alternative facility and/or establish additional manufacturing and supply arrangements. We may also need to establish additional or replacement

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manufacturers, potentially with little or no notice, in the event that one of our manufacturers fails to comply with FDA and/or other pharmaceutical manufacturing regulatory requirements. 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 may create a shortage of the product. It can take several years to qualify and validate a new contract manufacturer, and we cannot guarantee that we would be able to complete in a successful and timely manner the appropriate validation processes or obtain the necessary regulatory approvals for one or more additional or replacement manufacturers. Such alternate supply arrangements may not be available on commercially reasonable terms, or at all. Additionally, if we are unable to engage multiple suppliers to manufacture our products, we may have inadequate supply to meet the demand of our product.

In addition, OMS721 is a biologic drug product and any other product candidate from certain of our programs, including but not limited to MASP-2 and MASP-3, could be a biologic drug product, and we do not have the internal capability to produce biologics for use in clinical trials or on a commercial scale. There are only a limited number of manufacturers of biologic drug products and we cannot be certain that we can enter into supply agreements with a sufficient number of them on commercially reasonable terms, if at all. The regulatory requirements for commercial supply are more stringent than for clinical supply and we cannot guarantee that a contract manufacturer producing drug product for clinical trials will be able to complete in a successful and timely manner the appropriate validation processes or obtain the necessary regulatory approvals for commercial supply.

Our contract manufacturers may encounter difficulties with formulation, manufacturing, supply chain and/or release processes that could result in delays in clinical trials and/or regulatory submissions or that could impact adversely the commercialization of our products or product candidates, as well as in the initiation of enforcement actions by the FDA and other regulatory authorities. These difficulties also could result in the recall or withdrawal of a product from the market or a failure to have adequate supplies to meet market demand. If the safety of OMIDRIA or any product candidate supplied by contract manufacturers is compromised due to one or more of those contract manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to maintain regulatory approval of OMIDRIA, to continue sales and marketing of OMIDRIA or to obtain and maintain regulatory approval for one or more of our product candidates, which would harm our business and prospects significantly.

Any significant delays in the manufacture and/or supply of clinical or commercial supplies could materially harm our business, financial condition, results of operations and prospects.

Ingredients, excipients and other materials necessary to manufacture OMIDRIA or our product candidates may not be available on commercially reasonable terms, or at all, which may adversely affect the development and commercialization of OMIDRIA or those product candidates.

We and our third-party manufacturers must obtain from third-party suppliers the active pharmaceutical ingredients, excipients, and/or other raw materials plus primary and secondary packaging materials necessary for our contract manufacturers to produce OMIDRIA and our product candidates for our clinical trials and, to the extent approved or commercialized, for commercial distribution. Although we have entered or intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of active pharmaceutical ingredients, excipients and materials for OMIDRIA and our product candidates, we have not yet entered into agreements for the supply of all such ingredients, excipients or materials, and we may be unable to secure all such supply agreements or guarantees on commercially reasonable terms, if at all. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients, excipients or materials in a timely manner or in the quantities required. If we or our third-party manufacturers are unable to obtain the quantities of these ingredients, excipients or materials that are necessary for the manufacture of commercial supplies of OMIDRIA, our ability to generate revenue from the sale of OMIDRIA would be materially and adversely affected. Further, if we or our third-party manufacturers are unable to obtain active pharmaceutical ingredients, excipients and materials as necessary for our clinical trials or for the manufacture of commercial supplies of our product candidates, if approved, potential regulatory approval or commercialization would be delayed, which would materially and adversely affect our ability to generate revenue from the sale of our product candidates.

If our clinical trials are delayed, suspended or terminated, we may be unable to develop our product candidates on a timely basis, which would adversely affect our ability to obtain regulatory approvals, increase our development costs

and delay or prevent commercialization of approved products.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory agencies, institutional review boards or ethics committees, 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, the EMA or other foreign authorities regarding the scope or design of our clinical trials;

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- delays or the inability to obtain required approvals from institutional review boards, ethics committees or other responsible entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials for any reason including disease severity, trial protocol design, study eligibility criteria, patient population size (e.g., for orphan diseases or for some pediatric indications), proximity and/or availability of clinical trial sites for prospective patients, availability of competing therapies and clinical trials, regional differences in diagnosis and treatment, perceived risks and benefits of the product or product candidate, physician patient referral practices or the ability to monitor patients adequately before and after treatment;
- lower than anticipated retention rates of patients in clinical trials;
- the need to repeat or conduct additional clinical trials as a result of inconclusive or negative results, failure to replicate positive early clinical data in subsequent clinical trials, failure to deliver an efficacious dose of a product candidate, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol, an unacceptable study design or other problems;
- adverse findings in clinical or nonclinical studies related to the safety of our product candidates in humans;
- 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 inspection or review by the FDA or other regulatory authority of a clinical trial site or records of any clinical investigation;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials;
- the suspension by a regulatory agency of a trial put on a clinical hold; or
- the amendment of clinical trial protocols to reflect changes in regulatory requirements and guidance or other reasons as well as subsequent re-examination of amendments of clinical trial protocols by institutional review boards or ethics committees.

In addition, a clinical trial or development program may be suspended or terminated by us, the FDA or other regulatory authorities, or institutional review boards or ethics committees 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;
- the failure to remove a clinical hold in a timely manner (which we cannot predict with certainty), if at all;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks;
- inability to deliver an efficacious dose of a product candidate; or
- lack of adequate funding to continue the clinical trial or development program, 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 CROs and other third parties.

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. 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. Any delays in completing our clinical trials could increase our development costs, could slow down our product development and regulatory submission process, could delay our receipt of product revenue and could make it difficult to raise additional capital. 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, potentially harming our business.

Because we have a number of product candidates and development programs, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications for which there is a greater likelihood of obtaining regulatory approval and that may be more profitable, if approved.

We have limited resources and must focus on the product candidates and clinical and preclinical development programs that we believe are the most promising. As a result, we may forgo or delay the pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential and may not be able

to progress development programs as rapidly as otherwise possible. Further, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product through collaboration, license

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or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

Our preclinical programs may not produce product candidates that are suitable for clinical trials, our product candidates may not successfully complete clinical development and/or our product candidates may not be suitable for successful commercialization or generation of revenue through partnerships.

We must complete successfully preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before commencing clinical trials for any product candidate. Many pharmaceutical and biological product candidates do not successfully complete preclinical testing. There can be no assurance that positive results from preclinical studies will be predictive of results obtained from subsequent preclinical studies or clinical trials. Even if preclinical testing is successfully completed, we cannot be certain that any product candidates that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and such costs or an adverse outcome in such a proceeding may have a material negative effect on our financial condition, results of operations and/or stock price.

If we choose to go to court or take other enforcement action to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that our underlying patents are invalid or should not be enforced against that third-party. These lawsuits are expensive and consume time and other resources even if we are successful in stopping the infringement of our patents. In addition, a lawsuit could result in a finding that some or all of the claims of one or more of our relevant patents are invalid, unenforceable and/or not infringed, and could also result in a generic version of OMIDRIA being launched. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our patents. An adverse outcome in any such legal action could have a material negative effect on our financial condition, results of operations and/or stock price.

It may not be feasible to detect and undertake patent enforcement action to stop infringing activity by a number of individual entities, each on a small scale, such as compounding pharmacies. Further, our industry has produced a large number of patents and it is not always clear which patents cover various types of products or methods of use. A third party may claim that we or our contract manufacturers are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in the alleged infringing activity, including making, using or selling our products and product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we, or our contract manufacturers, are infringing the third party's patents and would order us or our contractors to stop the activities covered by the patents. In addition, if we or our contract manufacturers are found to have violated a third party's patent, we or our contract manufacturers could be ordered to pay damages to the other party. We have agreed to or may agree to indemnify our contract manufacturers against certain patent infringement claims and thus may be responsible for any of their costs associated with such claims and actions. If we were sued for patent infringement, we would need to demonstrate that our products and product candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we might be unable to do this. Proving invalidity, in particular, is difficult since it requires clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Although we have conducted searches of third-party patents with respect to our programs, we have not obtained written freedom to operate opinions for our programs and may not have identified all relevant third-party patents. Consequently, we cannot be certain that third-party patents containing claims covering our products, product candidates, programs, technologies or methods do not exist, have not been filed, or could not be filed or issued.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the capital necessary to continue our operations.

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It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our products and product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the U.S. Patent and Trademark Office or by a court or other trier of fact in the U.S., or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the U.S. or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and product candidates and/or materially harm our business.

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

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs, including our GPCR program;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will be sufficient to protect our technology, provide us with a basis for commercially viable products or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws; or
- if issued, the patents under which we hold rights may not be valid or enforceable.

In addition, to the extent that we are unable to obtain and maintain patent protection for one of our products or product candidates or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product or product candidate for follow-on indications.

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

The terms of our debt facility place restrictions on our operating and financial flexibility and, if we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

We have borrowed $125.0 million under the CRG Loan Agreement and pledged substantially all of our assets, including intellectual property, as collateral. The CRG Loan Agreement restricts our ability to, among other things, incur indebtedness, grant liens, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay cash dividends or make distributions, repurchase stock, license certain of our intellectual property on an exclusive basis and engage

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in significant business transactions such as a change of control. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities.

After 2018, the CRG Loan Agreement requires us to achieve either (a) certain minimum net revenue amounts through the end of 2021, which is $75.0 million for the 2019 calendar year, or (b) a minimum market capitalization threshold equal to the product of 3.0 multiplied by the aggregate principal amount of loans outstanding under the CRG Loan Agreement determined as of the fifth business day following announcement of earnings results for the applicable year (i.e., $375.0 million). In the event we do not achieve either of the minimum revenue amount or the minimum market capitalization threshold for a year, we can satisfy the requirement by raising additional funds through an equity or subordinated debt issuance and using the proceeds to pay down the loan balance by an amount equal to the difference between the minimum revenue amount for such year and the actual revenue amount for such year. We cannot guarantee that we will satisfy the 2019 annual revenue covenant in the CRG Loan Agreement or the alternative market capitalization covenant that will be calculated in February or March 2020.

The failure to satisfy these or other obligations under the CRG Loan Agreement would constitute an event of default. An event of default under the CRG Loan Agreement also includes the occurrence of any material adverse effect upon our business, condition (financial or otherwise), operations, performance or property taken as a whole. If there is an event of default under the CRG Loan Agreement, the lenders may have the right to accelerate all of our repayment obligations under the CRG Loan Agreement and to take control of our pledged assets, which include substantially all of our assets including our intellectual property. Upon the acceleration of the loan, we will be required to repay the loan immediately or to attempt to reverse the declaration through negotiation or litigation. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Any declaration 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 competitors may develop products that are less expensive, safer or more effective, or which may otherwise diminish or eliminate the success of any products that we may commercialize.

We may not achieve commercial success if our competitors, many of whom have significantly more resources and experience than we, market products that are safer, more effective, less expensive or faster to reach the market than OMIDRIA or any future products that we may develop and commercialize. Our competitors also may market a product that proves to be unsafe or ineffective, which may affect the market for our competing product, or future product, regardless of the safety or efficacy of our product. The failure of OMIDRIA or any other future product that we may market to compete effectively with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, our financial condition and our results of operations.

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

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies other than on the life of Gregory A. Demopulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, without having a readily available and appropriate replacement could delay the execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

We rely on highly skilled personnel and, if we are unable to retain or motivate key personnel or hire qualified personnel, we may not be able to maintain our operations or grow effectively.

Our performance is largely dependent on the talents and efforts of highly skilled individuals. Our future success depends on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization. If we are unable to hire and train a sufficient number of qualified employees for any reason, we may not be able to implement our current initiatives or grow effectively. We have in the past maintained a rigorous, highly selective and time-consuming hiring process. We believe that our approach to hiring has significantly contributed to our success to date. If we do not succeed in attracting qualified personnel and retaining and motivating

existing personnel, our existing operations may suffer and we may be unable to grow effectively.

We may encounter difficulties managing our growth, which could delay our business plans or adversely affect our results of operations.

To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to manage effectively the expansion of our operations or recruit and train additional qualified personnel. The

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physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Additionally, our inability to manage growth effectively could cause our operating costs to grow even faster than we currently are anticipating.

Product liability claims may damage our reputation and, if insurance proves inadequate, these claims may harm our business.

We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product's safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with commercialization of our products and product candidates. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain or maintain such insurance on acceptable terms or that we will be able to secure and maintain increased coverage for OMIDRIA or for our product candidates, if commercialization progresses, or that future claims against us will be covered by our product liability insurance. Further, our product liability insurance coverage may not reimburse us or may be insufficient to reimburse us for any or all expenses or losses we may suffer. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

We rely on third parties to conduct portions of our preclinical research and clinical trials. If these third parties do not perform as contractually required or otherwise expected, or if we fail to adequately supervise or monitor these parties, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We rely on third parties, such as CROs, medical and research institutions and clinical investigators, to conduct a portion of our preclinical research and assist us in conducting our clinical trials. Nonetheless, we are responsible for confirming that our preclinical research and clinical trials are conducted in accordance with applicable regulations, the relevant trial protocol and within the context of approvals by an institutional review board or ethics committee, and we may not always be successful in ensuring such compliance. Our reliance on these third parties does not relieve us of responsibility for ensuring compliance with FDA and other 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 commercialize or obtain regulatory approval for our product candidates.

We may need to maintain licenses for active ingredients from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates.

Should we decide to use active pharmaceutical ingredients in any of our product candidates that are proprietary to one or more third parties, such as our PDE7 program (OMS527), we would need to maintain licenses to those active ingredients from those third parties. If we are unable to continue to access rights to these active ingredients prior to conducting 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 maintain continued access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, or if we do not meet diligence or other obligations under the corresponding licenses, we may not be able to commercialize product candidates from these programs.

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

Our research operations produce hazardous waste products, which include chemicals and radioactive and biological materials. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and

disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply with applicable legal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. We generally contract with third parties for the disposal of such substances and store our low-level radioactive waste at our facility until the materials are no longer considered radioactive. We may be required to incur further costs to comply with current or future environmental and safety regulations. In addition, although we carry insurance, in the event of accidental contamination

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or injury from these materials, we could be held liable for any damages that result and any such liability could exceed our insurance coverage and other resources.

Cyber-attacks or other failures in telecommunications or information technology systems could result in information theft, data corruption and significant disruption of our business operations.

We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Risks Related to Our Common Stock

Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.

During the 12-month period ended June 30, 2018, our stock traded as high as $25.20 per share and as low as $8.36 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to numerous factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing shareholders would experience further dilution.

To the extent that we raise additional funds in the future by issuing equity securities, our shareholders would experience dilution, which may be significant and could cause the market price of our common stock to decline significantly. In addition, approximately 10,842,668 shares of common stock as of June 30, 2018 subject to outstanding options and warrants may become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements. Further, as of June 30, 2018 we also had approximately 2.3 million shares of common stock reserved for future issuance under our employee benefit plans that are not subject to outstanding options. If the holders of these outstanding options or warrants elect to exercise some or all of them, or if the shares subject to our employee benefit plans are issued and become eligible for sale in the public market, our shareholders would experience dilution and the market price of our common stock could decline.

Anti-takeover provisions in our charter documents and under Washington law could make an acquisition of us, which may be beneficial to our shareholders, difficult and prevent attempts by our shareholders to replace or remove our current management.

Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of shareholders to fill board vacancies and the ability of our board of directors to issue preferred stock without shareholder approval. In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of shareholders owning 10% or more of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively

provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

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

Our business requires significant funding. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Additionally, under the CRG Loan Agreement, we have agreed not to pay any cash dividends. Therefore, we currently do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a rise in the market price of our common stock, which is uncertain and unpredictable, will be the sole source of potential gain for shareholders in the foreseeable future, and an investment in our common stock for dividend income should not be relied upon.

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ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Unregistered Sales of Equity Securities. On April 12, 2018, we issued warrants to purchase an aggregate of 200,000 shares of common stock, or the CRG Warrants, to the CRG Loan Agreement lenders. For more information regarding the CRG Warrants, refer to Item 1.01 of our Current Report on Form 8-K that was filed with the SEC on April 13, 2018.

ITEM 6. EXHIBITS

Exhibit Number	Description
10.1(1)	Settlement Agreement, dated as of May 22, 2018, by and among Omeros Corporation and Lupin Ltd. and Lupin Pharmaceuticals, Inc.
12.1	Ratio of Earnings to Fixed Charges
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to Exhibit 10.1 of the registrant's Current Report on Form 8-K filed on May 24, 2018 (File No. 001-34475).

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OMEROS CORPORATION

Dated: August 9, 2018 /s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D.
President, Chief Executive Officer and Chairman of the Board of Directors

Dated: August 9, 2018 /s/ Michael A. Jacobsen
Michael A. Jacobsen
Vice President, Finance, Chief Accounting Officer and Treasurer