TREVENA INC
Form 10-Q
August 02, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2018

Or

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

For the transition period from to

Commission File Number 001-36193

Trevena, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	26-1469215 (I.R.S. Employer Identification No.)
955 Chesterbrook Boulevard, Suite 200 Chesterbrook, PA (Address of Principal Executive Offices)	 19087 (Zip Code)

Registrant's telephone number, including area code: (610) 354-8840

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 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, 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.:

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practical date.

Common Stock, $0.001 par value   Shares outstanding as of July 31, 2018: 76,082,280

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.

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Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10 Q (this “Quarterly Report”) contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but also are contained elsewhere in this Quarterly Report, as well as in sections such as “Risk Factors” that are incorporated by reference into this Quarterly Report from our most recent Annual Report on Form 10 K (the “Annual Report”). In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “pla “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue” and “ongoing,” or the negative of terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- our plans to develop and potentially commercialize our product candidates;
- our ability to fund future operating expenses, including any future launch of oliceridine, if approved, and capital expenditures with our current cash resources or to secure additional funding in the future;
- our planned nonclinical studies and clinical trials for our product candidates;
- the timing and likelihood of obtaining and maintaining regulatory approvals for our product candidates;
- the extent of clinical trials potentially required by the FDA for our product candidates;
- the clinical utility and market acceptance of our product candidates, particularly in light of existing and future competition;
- our sales, marketing, and manufacturing capabilities and strategy;
- our intellectual property position; and
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our ability to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives.

You should refer to the “Risk Factors” section of this Quarterly Report and our Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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PART I

ITEM 1. FINANCIAL STATEMENTS

TREVENA, INC.

Balance Sheets

(in thousands, except share and per share data)

	June 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 24,036	$ 16,557
Marketable securities	39,462	49,543
Alliance revenue receivable	2,250	—
Prepaid expenses and other current assets	1,543	1,393
Total current assets	67,291	67,493
Restricted cash	1,414	1,413
Property and equipment, net	3,613	3,805
Intangible asset, net	10	11
Total assets	$ 72,328	$ 72,722
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 592	$ 1,424
Accrued expenses and other current liabilities	3,651	4,303
Current portion of loans payable, net	12,494	12,425
Deferred revenue	3,000	—
Deferred rent	65	61
Total current liabilities	19,802	18,213
Loans payable, net	10,873	15,725
Capital leases, net of current portion	25	31
Deferred rent, net of current portion	2,926	3,006
Warrant liability	6	10
Other long term liabilities	—	1,104
Total liabilities	33,632	38,089
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 and 100,000,000 shares authorized June 30, 2018 and December 31, 2017, respectively, 73,507,985 and 62,310,795 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	74	62
Preferred stock—$0.001 par value; 5,000,000 shares authorized, none issued or outstanding at June 30, 2018 and December 31, 2017	—	—
Additional paid-in capital	414,457	392,103
Accumulated deficit	(375,815)	(357,490)
Accumulated other comprehensive loss	(20)	(42)

Total stockholders' equity	38,696	34,633
Total liabilities and stockholders' equity	$ 72,328	$ 72,722

See accompanying notes to financial statements.

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TREVENA, INC.

Statements of Operations and Comprehensive Loss (Unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30, 2018	2017	Six Months Ended June 30, 2018	2017
Revenue:				
Alliance revenue	$ 2,500	$ —	$ 2,500	$ —
Operating expenses:				
General and administrative	5,926	4,385	10,998	9,264
Research and development	5,128	15,499	9,726	31,595
Restructuring charges	41	—	64	—
Total operating expenses	11,095	19,884	20,788	40,859
Loss from operations	(8,595)	(19,884)	(18,288)	(40,859)
Other income (expense):				
Change in fair value of warrant liability	4	19	4	56
Net gain (loss) on asset disposals	(107)	1	116	1
Miscellaneous income	500	—	1,428	628
Interest income	226	163	425	337
Interest expense	(597)	(731)	(1,275)	(1,309)
Gain on foreign currency exchange	10	—	10	—
Total other income (expense)	36	(548)	708	(287)
Loss before income tax expense	(8,559)	(20,432)	(17,580)	(41,146)
Foreign income tax expense	(745)	—	(745)	—
Net loss attributable to common stockholders	$ (9,304)	$ (20,432)	$ (18,325)	$ (41,146)
Other comprehensive gain (loss), net:				
Unrealized gain (loss) on marketable securities	26	(8)	22	(59)
Other comprehensive gain (loss), net:	26	(8)	22	(59)
Comprehensive loss	$ (9,278)	$ (20,440)	$ (18,303)	$ (41,205)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.13)	$ (0.35)	$ (0.27)	$ (0.71)
Weighted average common shares outstanding, basic and diluted	69,664,994	58,381,868	67,127,711	57,642,379

See accompanying notes to financial statements.

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TREVENA, INC.

Statement of Stockholders’ Equity (Unaudited)

For the period from January 1, 2018 to June 30, 2018

(in thousands, except share data)

	Stockholders' Equity					
	Common Stock					
	Number of Shares	$0.001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance, January 1, 2018	62,310,795	$ 62	$ 392,103	$ (357,490)	$ (42)	$ 34,633
Stock-based compensation expense	—	—	2,785	—	—	2,785
Exercise of stock options	132,952	—	83	—	—	83
Issuance of common stock, net of issuance costs	11,064,238	12	19,486	—	—	19,498
Unrealized gain on marketable securities	—	—	—	—	22	22
Net loss	—	—	—	(18,325)	—	(18,325)
Balance, June 30, 2018	73,507,985	$ 74	$ 414,457	$ (375,815)	$ (20)	$ 38,696

See accompanying notes to financial statements.

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TREVENA, INC.

Statements of Cash Flows (Unaudited)

(in thousands)

	Six Months Ended June 30, 2018	2017
Operating activities:		
Net loss	$ (18,325)	$ (41,146)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	340	158
Stock-based compensation	2,785	3,687
Noncash interest expense on loans	446	530
Revaluation of warrant liability	(4)	(56)
Amortization (accretion) of bond premium (discount) on marketable securities	(25)	316
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,400)	(1,674)
Accounts payable, accrued expenses and other liabilities	(1,560)	(9,563)
Deferred revenue	3,000	—
Net cash used in operating activities	(15,743)	(47,748)
Investing activities:		
Purchases of property and equipment	(147)	(2,019)
Maturities of marketable securities	32,550	48,443
Purchases of marketable securities	(22,422)	(32,646)
Net cash provided by investing activities	9,981	13,778
Financing activities:		
Proceeds from exercise of common stock options	83	355
Proceeds from issuance of common stock, net	19,498	13,687
Capital lease payments	(6)	(3)
Proceeds from loans payable, net	—	9,921
Repayments of loans payable, net	(6,333)	—
Net cash provided by financing activities	13,242	23,960
Net increase (decrease) in cash and cash equivalents	7,480	(10,010)
Cash, cash equivalents and restricted cash—beginning of period	17,970	25,459
Cash, cash equivalents and restricted cash—end of period	$ 25,450	$ 15,449
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 827	$ 778
Fair value of common stock warrants issued	$ —	$ 184

See accompanying notes to financial statements.

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TREVENA, INC.

Notes to Unaudited Financial Statements

June 30, 2018

1. Organization and Description of the Business

Trevena, Inc., or the Company, was incorporated in Delaware as Parallax Therapeutics, Inc. on November 9, 2007. The Company began operations in December 2007, and its name was changed to Trevena, Inc. on January 3, 2008. The Company is a biopharmaceutical company developing innovative therapies based on breakthrough science to benefit patients and healthcare providers confronting serious medical conditions. The Company operates in one segment and has its principal office in Chesterbrook, Pennsylvania.

Since commencing operations in 2007, the Company has devoted substantially all of its financial resources and efforts to research and development, including preclinical studies and clinical trials. The Company has never been profitable and has not yet commenced commercial operations. In January 2018, the United States Food and Drug Administration, or FDA, accepted the new drug application, or NDA, submission for oliceridine, the Company's lead product candidate. The FDA also indicated that the Prescription Drug User Fee Act, or PDUFA, review date for the oliceridine NDA is November 2, 2018 and that it plans to hold an advisory committee meeting, likely in October 2018, to discuss the NDA. If oliceridine ultimately receives regulatory approval, the Company plans to commercialize it in the United States, either on its own or with a commercial partner, for use in acute care settings such as hospitals and ambulatory surgery centers; outside the United States, the Company plans to commercialize oliceridine in certain countries with commercial partners and, in the second quarter of 2018, the Company announced license agreements with partners in South Korea and China. See Notes 7 and 8 for additional information.

Since the Company’s inception, the Company has incurred losses and negative cash flows from operations. At June 30, 2018, the Company had an accumulated deficit of $375.8 million. The Company’s net loss was $18.3 million and $41.1 million for the six months ended June 30, 2018 and 2017, respectively. The Company expects its cash and cash equivalents of $24.0 million and marketable securities of $39.5 million as of June 30, 2018, together with interest thereon, as well as proceeds from the sale of shares of common stock under the Company’s at the market, or ATM, sales agreement with Cowen and Company, LLC, or Cowen, and from the receipt of $2.3 million related to an upfront payment from ex-U.S. licensing activities in China between June 30, 2018 and the date of this filing, to be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months following the date of this filing. If approved by FDA on November 2, 2018, and following Drug Enforcement Administration, or DEA, Scheduling, the Company expects to launch oliceridine in the United States in the first half of 2019. The extent of the Company’s commercial efforts for oliceridine, including the number of sales representatives and medical science liaisons at launch, will depend to a significant extent on the success of the Company’s fundraising efforts between the date of this filing and the launch date.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP. Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification, or ASC, and Accounting Standards Update, or ASU, of the Financial Accounting Standards Board, or FASB. The Company’s functional currency is the U.S. dollar.

The financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company's balance sheet as of June 30, 2018, its results of operations and its comprehensive loss for the three and six months ended June 30, 2018 and 2017, its statement of stockholders' equity for the period from January 1, 2018 to June 30, 2018, and its cash flows for the six months ended June 30, 2018 and 2017. The information included in this Quarterly Report on Form 10 Q should be read in conjunction with the financial statements and accompanying notes included in the Company's most recent Annual Report on Form 10 K for the year ended December 31, 2017. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies. The financial data and other information disclosed in these notes related to the six

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months ended June 30, 2018 and 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2018, any other interim periods, or any future year or period.

Revenue

In accordance with FASB's ASC 606, Revenue from Contracts with Customers, or ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

(i) identify the contract(s) 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) the entity satisfies a performance obligation.

The Company applies the five-step model to contracts when it determines that it is probable it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company's balance sheet. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date are classified as Current portion of deferred revenue. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as Deferred revenue, net of current portion.

Alliance Revenues

The Company's revenues have primarily been generated through licensing arrangements. The terms of these agreements typically include payment to the Company of one or more of the following: nonrefundable, up-front license fees; regulatory and commercial milestone payments; payments for manufacturing supply services; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps:

(i) identification of the promised goods or services in the contract;
(ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
(iii) measurement of the transaction price, including the constraint on variable consideration;
(iv) allocation of the transaction price to the performance obligations; and
(v) recognition of revenue when (or as) the Company satisfies each performance obligation.

See Note 8 for additional details surrounding the Company's licensing arrangements.

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The Company also assesses whether there is an option in a contract to acquire additional goods or services. An option gives rise to a performance obligation only if the option provides a material right to the customer that it would not receive without entering into that contract. Factors that the Company considers in evaluating whether an option represents a material right include, but are not limited to: (i) the overall objective of the arrangement, (ii) the benefit the collaborator might obtain from the arrangement without exercising the option, (iii) the cost to exercise the option (e.g. priced at a significant and incremental discount) and (iv) the likelihood that the option will be exercised. With respect to options determined to be performance obligations, the Company recognizes revenue when those future goods or services are transferred or when the options expire.

The Company’s revenue arrangements may include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes regulatory or commercial milestone payments, the Company evaluates whether each milestone is considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received.At each reporting period, the Company assesses the probability of achievement of each milestone under its current agreements.

Research and Development Activities: Under the Company’s current collaboration and license arrangements, if the Company is entitled to reimbursement for costs for services provided by the Company, it expects such reimbursement would be an offset to research and development expenses.

Royalties: If the Company is entitled to receive sales-based royalties from its collaborator, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, provided the reported sales are reliably measurable, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Manufacturing Supply and Research Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

The Company receives payments from its licensees based on schedules established in each contract. Upfront payments are recorded as deferred revenue upon receipt, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

Income Taxes

In accordance with ASC 270, Interim Reporting, and ASC 740, Income Taxes, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the six months ended June 30, 2018, the Company recorded foreign income tax expense related to withholdings associated with our ex-U.S. licensing activities. For the six months ended June 30, 2017, the Company recorded no tax expense or benefit due to the expected

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2017 loss and its historical losses. The Company has not recorded its net deferred tax asset as of either June 30, 2018 or December 31, 2017 because it maintained a full valuation allowance against all deferred tax assets as of these dates as management has determined that it is not more likely than not that the Company will realize these future tax benefits. As of June 30, 2018 and December 31, 2017, the Company had no uncertain tax positions.

In December 2017, the Tax Cuts and Jobs Act, or TCJA, was signed into law. Among other things, the TCJA permanently lowers the corporate federal income tax rate to 21% from the existing maximum rate of 35%, effective for tax years including or commencing January 1, 2018. As a result of the reduction of the corporate federal income tax rate to 21%, GAAP requires companies to revalue their deferred tax assets and deferred tax liabilities as of the date of enactment, with the resulting tax effects accounted for in the reporting period of enactment. This revaluation resulted in a provision of $27.6 million to income tax expense in and a corresponding reduction in the valuation allowance in the fourth quarter of 2017. As a result, there was no impact to the Company’s statement of operations and comprehensive loss as a result of reduction in tax rates. The Company’s preliminary estimate of the TCJA and the remeasurement of its deferred tax assets and liabilities is subject to the finalization of management’s analysis related to certain matters, such as developing interpretations of the provisions of the TCJA, changes to certain estimates and the filing of the Company’s tax returns. U.S. Treasury regulations, administrative interpretations or court decisions interpreting the TCJA may require further adjustments and changes in the Company’s estimates. The final determination of the TCJA and the remeasurement of the Company’s deferred assets and liabilities will be completed as additional information becomes available, but no later than one year from the enactment of the TCJA.

Recently Adopted Accounting Standards

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, or SAB 118, which provides guidance on accounting for the tax effects of the TCJA. SAB 118 was issued to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act and allows the Company to record provisional amounts during a measurement period not to extend beyond one year of the TCJA enactment date. The Company was able to reasonably estimate certain effects of the TCJA as of December 31, 2017 and has not changed the preliminary estimates as of June 30, 2018.

In May 2017, the FASB issued ASU No. 2017-09, Stock Compensation - Scope of Modification Accounting, which amends the scope of modification accounting for share-based payment arrangements. The amendment provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard is effective for fiscal years beginning after December 15, 2017. The adoption of this standard did not have an impact on the Company’s consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230), to clarify how certain cash receipts and payments should be presented in the statement of cash flows. The standard is effective for annual periods beginning after December 15, 2017 and interim periods within that reporting period. The adoption of this standard did not have an impact on the Company’s consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers. ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer in an amount reflecting the consideration it expects to receive in exchange for those goods or services. Additionally, in March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers, Principal versus Agent Considerations. ASU 2016-08 amends the principal versus agent guidance in ASU 2014-09 to clarify how an entity should identify the unit of accounting for the principal versus agent evaluation and how it should apply the control principal to certain types of arrangements. The effective date for both standards is January 1, 2018. The Company adopted these standards on January 1, 2018 and elected the modified retrospective transition method, meaning the cumulative effect of applying the new guidance, if any, was recognized at that date as an adjustment to the opening accumulated deficit balance. There was no impact to the Company's financial statements upon adoption, as the Company did not have any contracts with customers prior to, or, as of the adoption date.

Recent Accounting Standards Not Yet Adopted

In February 2018, the FASB issued ASU 2018-02, Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, which provides the option to reclassify stranded tax effects within accumulated other

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comprehensive income to retained earnings. This option would be available in each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act (or a portion thereof) is recorded. This is effective for the Company beginning after December 15, 2018, with early adoption permitted. These amendments should be applied in the period of adoption or retrospectively to each period in which the effect of the change in the U.S federal corporate income tax rate in the Tax Cuts and Jobs Act is recognized. The Company is evaluating the effect this standard will have on its financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which requires lessees to record most leases on their balance sheets and disclose key information about leasing arrangements in an effort to increase transparency and comparability among organizations. The standard is effective for annual periods beginning after December 15, 2018 and interim periods within that reporting period. Early adoption is permitted. The Company is evaluating the effect this standard will have on its financial statements and related disclosures.

3. Fair Value of Financial Instruments

ASC Topic 820, Fair Value Measurement, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company’s own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company’s assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2 Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

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Cash, Cash Equivalents and Marketable Securities

The following table presents fair value of the Company's cash, cash equivalents, and marketable securities as of June 30, 2018 and December 31, 2017 (in thousands):

	June 30, 2018						
	Adjusted Cost	Unrealized Gains	Unrealized Loss	Fair Value	Cash and Cash Equivalents	Restricted Cash	Marketable Securities
Cash	$ 8,704	$ —	$ —	$ 8,704	$ 7,290	$ 1,414	$ —
Level 1 (1):							
Money market funds	16,746	—	—	16,746	16,746	—	—
U.S. treasury securities	4,983	—	(1)	4,982	—	—	4,982
Subtotal	21,729	—	(1)	21,728	16,746	—	4,982
Level 2 (2):							
U.S. government agency securities	34,499	—	(19)	34,480	—	—	34,480
Total	$ 64,932	$ —	$ (20)	$ 64,912	$ 24,036	$ 1,414	$ 39,462

	December 31, 2017						
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Restricted Cash	Marketable Securities
Cash	$ 6,783	$ —	$ —	$ 6,783	$ 5,370	$ 1,413	$ —
Level 1 (1):							
Money market funds	11,187	—	—	11,187	11,187	—	—
U.S. treasury securities	1,991	—	—	1,991	—	—	1,991
Subtotal	13,178	—	—	13,178	11,187	—	1,991
Level 2 (2):							
U.S. government agency securities	47,594	—	(42)	47,552	—	—	47,552
Total	$ 67,555	$ —	$ (42)	$ 67,513	$ 16,557	$ 1,413	$ 49,543

(1) The fair value of Level 1 securities is estimated based on quoted prices in active markets for identical assets or liabilities.

(2) The fair value of Level 2 securities is estimated based on observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

The Company classifies investments available to fund current operations as current assets on its balance sheets. As of June 30, 2018, the Company did not hold any investment securities exceeding a one-year maturity.

Unrealized gains and losses on marketable securities are recorded as a separate component of accumulated other comprehensive income (loss) included in stockholders' equity. Realized gains (losses) are included in interest income (expense) in the statement of operations and comprehensive income (loss) on a specific identification basis. The Company did not record any realized gains or losses during the three and six months ended June 30, 2018 and 2017. To date, the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value.

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers between Level 2 and Level 3 during the six months ended June 30, 2018 or the year ended December 31, 2017.

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4. Loans Payable

In September 2014, the Company entered into a loan and security agreement with Oxford Finance LLC and Pacific Western Bank (formerly Square 1Bank) (together, the lenders), pursuant to which the lenders agreed to lend the Company up to $35.0 million in a three-tranche series of term loans (Term Loans A, B, and C). Upon initially entering into the agreement, the Company borrowed $2.0 million under Term Loan A. In April 2015, the Company amended the agreement with the lenders to change the draw period for Term Loan B. In December 2015, the Company further amended the agreement with the lenders to, among other things, change the draw period for Term Loan C, modify the interest only period, and modify the maturity date of the loan. In December 2015, the Company borrowed the Term Loan B tranche of $16.5 million. The Company's ability to draw an additional $16.5 million under Term Loan C was subject to the satisfaction of one or more specified triggers related to the results of the Company's Phase 2b clinical trial of TRV027, which were announced in May 2016. Although those triggers were not attained, in December 2016, the Company and the lenders modified the terms and conditions under which the Company could exercise an option to draw $10.0 million of Term Loan C. In March 2017, the Company borrowed the Term Loan C tranche of $10.0 million.

Borrowings under Term Loans A and B accrue interest at a fixed rate of 6.50% per annum. Borrowings under Term Loan C accrue interest at a fixed rate of 6.98% per annum. The Company was required to make payments of interest only on borrowings under the loan agreement on a monthly basis through and including January 1, 2018. Payments of principal in equal monthly installments and accrued interest began January 1, 2018 and will continue to be due until the loan matures on March 1, 2020. Upon the last payment date of the amounts borrowed under the agreement, the Company will be required to pay a final payment fee equal to 6.6% of the aggregate amounts borrowed, which is recorded as interest expense over the term of the loans payable. In addition, if the Company repays Term Loan A, Term Loan B, or Term Loan C prior to the applicable maturity date, it will pay the lenders a prepayment fee of 1.0% of each of Term Loans A and B, and 2.0% of Term Loan C, if the prepayment occurs on or between April 1, 2018 and March 31, 2019, and 1.0% of Term Loan C, if the prepayment occurs on or after April 1, 2019.

The Company's obligations under the loan and security agreement are secured by a first priority security interest in substantially all of the assets of the Company, including the Company's cash, cash equivalents, and marketable securities but excluding the Company's intellectual property (together, the collateral). The Company has agreed not to pledge or otherwise encumber its intellectual property, other than through grants of certain permitted non-exclusive or exclusive licenses or other conveyances of its intellectual property.

The loan and security agreement includes affirmative and restrictive covenants, including: (a) financial reporting requirements; (b) limitations on the incurrence of indebtedness; (c) limitations on liens; (d) limitations on certain merger and acquisition transactions; (e) limitations on dispositions of certain assets; (f) limitations on fundamental corporate changes (including changes in control); (g) limitations on investments; (h) limitations on payments and distributions and (i) other covenants. The agreement also contains certain events of default, including for payment defaults, breaches of covenants, a material adverse change in the Company's business, operations or condition (financial or otherwise), a material impairment in the value of the collateral or in the prospect of repayment of the Company's obligations to the lender, certain levies, attachments and other restraints on the Company's business, insolvency, defaults under other agreements and misrepresentations. Upon an event of default, the lenders have the right to foreclose upon the available collateral, including the Company's existing cash and cash equivalents and marketable securities.

In connection with entering into the agreement, the Company issued to the lenders and the placement agent warrants to purchase an aggregate of 7,678 shares of Trevena's common stock, of which 5,728 shares remain outstanding as of June 30, 2018. These detachable warrant instruments have qualified for equity classification and have been allocated upon the relative fair value of the base instrument and the warrants, according to the guidance of ASC 470-20-25-2.

These warrants are exercisable immediately and have an exercise price of $5.8610 per share. The warrants may be exercised on a cashless basis and will terminate on the earlier of September 19, 2024 or the closing of a merger or consolidation transaction in which the Company is not the surviving entity. In connection with the draw of Term Loan B, the Company issued to the lenders and the placement agent additional warrants to purchase an aggregate of 34,961 shares of Trevena common stock, all of which remain outstanding at June 30, 2018. These warrants have substantially the same terms as those noted above, have an exercise price of $10.6190 per share and an expiration date of December 23, 2025. In connection with draw of Term Loan C, the Company issued to the lenders and placement agent additional warrants to purchase an aggregate of 62,241 shares of the Company’s common stock, all of which remain

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outstanding at June 30, 2018. These warrants have substantially the same terms as those noted above, and have an exercise price of $3.6150 per share and an expiration date of March 31, 2027.

As of June 30, 2018, borrowings of $22.2 million attributable to Term Loans A, B, and C remain outstanding. Interest expense of $0.8 million and $0.8 million was recorded during the six months ended June 30, 2018 and 2017, respectively. The Company incurred lender and third party costs of $1.0 million related to the issuance of its term loans. Per ASU 2015 3, Interest-Imputation of Interest, debt discount and debt issuance costs are to be presented as a contra-liability to the debt on the balance sheet. These costs will be amortized to interest expense over the life of the loans using the effective interest method. Immaterial amounts of debt discount and debt issuance cost were amortized to interest expense during the three and six months ended June 30, 2018 and 2017, respectively.

The following table summarizes how the issuance of Term Loans A, B, and C are reflected on the balance sheet at June 30, 2018 and December 31, 2017 (in thousands):

	June 30, 2018	December 31, 2017
Gross proceeds	$ 22,167	$ 28,500
Debt discount and debt issuance costs	1,200	(350)
Carrying value	23,367	28,150
Current portion of loans payable, net	12,494	12,425
Loans payable, net	$ 10,873	$ 15,725

The accretion of the final fee payment is presented as part of Debt discount and debt issuance costs, a component of loans payable, as of June 30, 2018 and as other long term liabilities as of December 31, 2017.

5. Stockholders' Equity

Equity Offerings

On December 14, 2015, the Company entered into an ATM sales agreement with Cowen, or the Prior ATM Agreement, to offer and sell, from time to time at the Company's sole discretion, shares of its common stock, having an aggregate offering price of up to $75.0 million through Cowen as its sales agent. Sales under the Prior ATM Agreement are deemed to be "at the market offerings", as defined in Rule 415 under the Securities Act of 1933, as amended, or the Securities Act. Under the Prior ATM Agreement, the Company was required to pay Cowen a commission of up to three percent of the gross sales proceeds and provided Cowen with customary indemnification rights. In the six months ended June 30, 2018, the Company issued and sold 11,064,238 shares of common stock under the Prior ATM Agreement at a weighted average price per share of $1.81. The net offering proceeds to the Company were approximately $19.5 million after deducting related expenses, including commissions. The Prior ATM Agreement terminated on June 29, 2018 when the Company's Registration Statement on Form S-3 (File No.

333-225685) was declared effective by the SEC. Accordingly, as of June 30, 2018, there was no remaining capacity available under this ATM facility.

On June 15, 2018, the Company entered into a new ATM sales agreement with Cowen to offer and sell, from time to time at the Company's sole discretion, shares of its common stock, having an aggregate offering price of up to $50.0 million through Cowen as its sales agent. Sales of the shares are deemed to be "at the market offerings", as defined in Rule 415 under the Securities Act. The Company is required to pay Cowen a commission of up to three percent of the gross sales proceeds and has provided Cowen with customary indemnification rights. During the second quarter of 2018, no sales were made under this ATM facility and the entire $50 million capacity remained available as of June 30, 2018.

Equity Incentive Plans

The Company utilizes equity incentive plans to grant various forms of stock options and restricted stock to eligible employees, directors and consultants to the Company. Under all of such plans, the amount, terms of grants and exercisability provisions are determined by the board of directors or its designee. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the board of directors. Vesting generally occurs over a period of not greater than 4 years. For performance-based stock awards, we recognize expense when achievement of the performance factor is probable, over the requisite service period.

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The estimated grant-date fair value of the Company's stock-based awards is amortized ratably over the awards' service periods. Stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Research and development	$ 386	$ 735	$ 744	$ 1,441
General and administrative	901	1,158	2,041	2,246
Total stock-based compensation	$ 1,287	$ 1,893	$ 2,785	$ 3,687

	Options Outstanding		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Balance, December 31, 2017	8,624,223	$ 5.22	7.17
Granted	3,085,125	1.79	
Exercised	(132,952)	0.63	
Forfeited/Cancelled	(2,190,948)	4.31	
Balance, June 30, 2018	9,385,448	$ 4.37	7.35
Vested or expected to vest at June 30, 2018	9,385,448	$ 4.37	7.35
Exercisable at June 30, 2018	4,225,244	$ 5.46	5.25

The intrinsic value of the options exercisable as of June 30, 2018 was $0.2 million, based on the Company's closing stock price of $1.44 per share and a weighted average exercise price of $5.46 per share. At June 30, 2018, there was $9.8 million of total unrecognized compensation expense related to unvested options that will be recognized over the weighted average remaining period of 2.25 years.

The Company uses the Black-Scholes option pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, including estimating the fair value of the Company's common stock, assumptions related to the expected price volatility of the Company's stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's common stock.

The per-share weighted-average grant date fair value of the options granted to employees and directors during the six months ended June 30, 2018 and 2017 was estimated at $1.19 and $3.20 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

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	Six Months Ended June 30, 2018		2017	
Expected term of options (in years)	5.8		6.2	
Risk-free interest rate	2.7	%	2.1	%
Expected volatility	74.9	%	75.7	%
Dividend yield	0	%	0	%

Shares Available for Future Grant

At June 30, 2018, the Company has the following shares available to be granted under its equity incentive plans:

	2013 Plan	Inducement Plan
Available at December 31, 2017	991,613	293,000
Authorized	2,492,431	—
Granted	(2,763,125)	(322,000)
Forfeited/Cancelled	2,074,823	116,125
Available at June 30, 2018	2,795,742	87,125

Shares Reserved for Future Issuance

At June 30, 2018, the Company has reserved the following shares of common stock for issuance:

Stock options outstanding under 2013 Plan	8,972,573
Shares available for future grant under 2013 Plan	2,795,742
Stock options outstanding under Inducement Plan	412,875
Shares available for future grant under Inducement Plan	87,125
Employee stock purchase plan	225,806
Warrants outstanding	123,091
Total shares of common stock reserved for future issuance	12,617,212

6. Commitments and Contingencies

Legal Proceedings

The Company is not involved in any legal proceeding that it expects to have a material effect on its business, financial condition, results of operations and cash flows.

7. Licensing Arrangements

License and Commercialization Agreement with Pharmbio Korea Inc.

In April 2018, the Company entered into an exclusive license agreement with Pharmbio Korea Inc., or Pharmbio, for the development and commercialization of oliceridine for the management of moderate to severe acute pain in South Korea. Under the terms of the agreement, the Company received an upfront, non-refundable cash payment of $3.0 million in connection with execution of the agreement, a cash commercial milestone of up to $0.5 million if oliceridine is approved in South Korea and tiered royalties on product sales in South Korea ranging from high single digits to 20%, less applicable withholding taxes. As part of the agreement, Trevena also granted Pharmbio an option to manufacture oliceridine, on a non-exclusive basis, for the development and commercialization of the product in South Korea, subject to a separate arrangement to be entered into if Pharmbio exercises the option.

In accordance with the terms of the agreement, Pharmbio is solely responsible for all development and regulatory activities in South Korea. The parties have formed a Joint Development Committee with equal representation from the Company and Pharmbio to provide overall coordination and oversight of the development of oliceridine in

South Korea. The parties also agreed to form a Joint Manufacturing and Commercialization Committee at least six months prior to the anticipated date of regulatory approval of oliceridine in South Korea to provide overall coordination and oversight of the manufacture and commercialization of oliceridine in South Korea.

See Note 8 for accounting analysis under ASC 606.

License Agreement with Jiangsu Nhwa Pharmaceutical Co. Ltd.

In April 2018, the Company also entered into an exclusive license agreement with Jiangsu Nhwa Pharmaceutical Co. Ltd., or Nhwa, for the development and commercialization of oliceridine for the management of moderate to severe acute pain in China. Under this agreement, the Company will receive an upfront, non-refundable cash payment of $2.5 million (less applicable withholding taxes of $0.3 million) and is eligible to receive cash milestone payments of $3.0 million upon regulatory approval of oliceridine in each of the United States and China, up to an additional $6.0 million of commercialization milestones based on product sales levels in China, and a ten percent royalty on all net product sales in China, less applicable withholding taxes. As part of the agreement, Trevena also granted Nhwa an option to manufacture oliceridine, on an exclusive basis in China, for the development and commercialization of the product in China. As of June 30, 2018, Nhwa has elected to exercise this manufacturing option and a separate agreement will be entered into. The Company received the upfront cash payment, net of withholdings, in July 2018.

In accordance with the terms of the agreement, Nhwa is solely responsible for all development and regulatory activities in China. The parties have formed a Joint Development Committee with equal representation from the Company and Nhwa to provide overall coordination and oversight of the development of oliceridine in China. The parties also agreed to form a Joint Manufacturing and Commercialization Committee at least six months prior to the anticipated date of regulatory approval of oliceridine in China to provide overall coordination and oversight of the manufacture and commercialization of oliceridine in China.

See Note 8 for accounting analysis under ASC 606.

8. Revenue

The Company accounts for revenue under FASB's ASC 606, Revenue from Contracts with Customers, or ASC 606, under which revenue is recognized when, or as, performance obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers.

Alliance Revenue

Alliance revenue for the three months ended June 30, 2018 represents revenue from contracts with customers in licensing arrangements accounted for in accordance with ASC Topic 606, which the Company adopted in the first quarter of 2018, as more fully described in Note 2 and Note 7. There was no previously recorded Alliance revenue.

For the three and six months ended June 30, 2018, Alliance revenue in the accompanying statements of operations and comprehensive loss is comprised of the following:

	Three Months Ended June 30, 2018	Six Months Ended June 30, 2018
Pharmbio Korea Inc.	$ —	$ —
Jiangsu Nhwa Pharmaceutical Co. Ltd.	2,500	2,500
	$ 2,500	$ 2,500

There was no Alliance revenue activity in 2017. The 2018 Alliance revenue recognized relates to the upfront payments received from Nhwa once the related performance obligation was satisfied. This performance obligation was satisfied once the Company had transferred the license and know-how to Nhwa and Nhwa could begin to benefit from this transfer. The revenue related to the Pharmbio agreement has been deferred, based on the date at which the license

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and know-how was transferred, and will be recognized in the third quarter of 2018, at the time the Company completed its performance obligation. The Company determined that participation in the Joint Development Committees and Joint Manufacturing and Commercialization Committees were deemed immaterial in the context of the contract.

The income tax expense resulting from these transactions represents foreign withholding taxes as a result of alliance revenue from the contracts. As the Company has incurred losses in recent years, no material U.S. federal, state, or foreign income taxes have been accrued.

9. Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Basic and diluted net loss per common share calculation:				
Net loss	$ (9,304)	$ (20,432)	$ (18,325)	$ (41,146)
Net loss attributable to common stockholders	$ (9,304)	$ (20,432)	$ (18,325)	$ (41,146)
Weighted average common shares outstanding	69,664,994	58,381,868	67,127,711	57,642,379
Net loss per share of common stock - basic and diluted	$ (0.13)	$ (0.35)	$ (0.27)	$ (0.71)

The following outstanding securities at June 30, 2018 and 2017 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	June 30,	
	2018	2017
Options outstanding	9,385,448	8,520,152
Warrants	123,091	123,091
Total	9,508,539	8,643,243

10. Other Comprehensive Loss

The following table presents changes in the components of accumulated other comprehensive loss (in thousands):

Balance, December 31, 2017	$ (42)
Net unrealized gain on marketable securities	22

Balance, June 30, 2018	$ (20)

There were no reclassifications out of accumulated other comprehensive loss during the six months ended June 30, 2018 and 2017. There was no tax effect during the three six and months ended June 30, 2018 and 2017.

11. Restructuring Charges

On October 11, 2017, upon the approval of the Company's Board of Directors, the Company announced a restructuring and reduction in force of approximately 30% of the Company's workforce, or 21 employees. As part of this restructuring, the Company also halted its investment in early stage research. The Company incurred pre-tax restructuring charges of $1.8 million during the year ended December 31, 2017, primarily related to severance and personnel related costs in addition to lease termination payments. As of December 31, 2017, the Company’s restructuring liability totaled $1.1 million. During the three and six months ended June 30, 2018, the Company made severance payments totaling $0.2 million and $0.9 million, respectively. As of June 30, 2018, the Company’s restructuring liability totals $0.2 million, which has been recorded within accrued expenses on the Company’s balance sheet.

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

The following discussion and analysis of our financial condition and result of operations should be read in conjunction with our unaudited financial statement and related notes that appear in Item 1 of this Quarterly Report on Form 10 Q and with our audited financial statements and related notes for the year ended December 31, 2017, which are included in our Annual Report on Form 10 K filed with the Securities and Exchange Commission, or SEC, on March 7, 2018. Unless the context otherwise requires, we use the terms "Trevena," "company," "we," "us" and "our" to refer to Trevena, Inc.

Overview

Using our proprietary product platform, we have identified and are developing the following product candidates:

- Oliceridine injection: We are developing oliceridine, a G protein biased ligand of the µ opioid receptor, for the management of moderate-to-severe acute pain where intravenous, or IV, administration is preferred. In February 2017, we announced positive top-line results from our Phase 3 APOLLO-1 and APOLLO-2 pivotal efficacy studies of oliceridine in moderate-to-severe acute pain following bunionectomy and abdominoplasty, respectively. In both studies, all dose regimens achieved their primary endpoint of statistically greater analgesic efficacy than placebo, as measured by responder rate. In July 2017, we announced that we had completed enrollment in the Phase 3 open-label ATHENA safety study to support the new drug application, or NDA, for oliceridine. In the study, 768 patients were administered oliceridine to manage pain associated with a wide range of procedures and diagnoses. In January 2018, we announced that the United States Food and Drug Administration, or FDA, had accepted the NDA we submitted for oliceridine. The FDA also indicated that the Prescription Drug User Fee Act, or PDUFA, review date for the oliceridine NDA is November 2, 2018 and that it plans to hold an advisory committee meeting, likely in October 2018, to discuss the NDA. If oliceridine ultimately receives regulatory approval, we plan to commercialize it in the United States, either on our own or with a commercial partner, for use in acute care settings such as hospitals and ambulatory surgery centers; outside the United States, we plan to commercialize oliceridine in certain countries with a commercial partner and, in the second quarter of 2018, we announced license agreements with partners in South Korea and China. If approved by FDA on November 2, 2018, and following DEA scheduling, we expect to launch oliceridine in the United States in the first half of 2019.
- TRV250: We are developing TRV250, a G protein biased ligand targeting the -receptor, as a compound with a potential first-in-class, non-narcotic mechanism for the treatment of acute migraine. TRV250 also may have utility in a range of other central nervous system, or CNS, indications. Because TRV250 selectively targets the -receptor, we believe it will not have the addiction liability of conventional opioids or other µ-opioid related adverse effects like those seen with morphine or oxycodone. In June 2018, we announced the successful completion of our first-time-in-human Phase 1 study of TRV250. Data from this healthy volunteer study showed safety, tolerability, and pharmacokinetics supporting the advancement of TRV250 to Phase 2 proof of concept evaluation in patients, subject to available funds.

We also have identified and have completed the initial Phase 1 studies for TRV734, an orally administered new chemical entity expected to be used for first-line treatment of moderate-to-severe acute and chronic pain. In August 2018, we announced that we are supporting efforts by the National Institute on Drug Abuse to evaluate TRV734 as a potential maintenance treatment for opioid dependence. We intend to continue to focus our efforts for TRV734 on securing a development and commercialization partner for this asset. We also are evaluating a set of novel S1P modulators that may offer a new, non-narcotic approach to managing chronic pain. We expect to complete characterization of the lead compounds in 2018 to determine if any merit IND-enabling studies to support Phase 1 clinical trials.

On April 5, 2018, we announced that Maxine Gowen, Ph.D., Trevena's President and Chief Executive Officer, will retire on October 1, 2018. The Board of Directors has selected Carrie L. Bourdow, who currently serves as

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Trevena's Executive Vice President and Chief Operating Officer, to be the Company's next President and Chief Executive Officer, effective October 1, 2018. Dr. Gowen will continue to serve on the Trevena Board of Directors following the date of her resignation.

Since our incorporation in late 2007, our operations have included organizing and staffing our company, business planning, raising capital, and discovering and developing our product candidates. We have financed our operations primarily through private placements and public offerings of our equity securities and debt borrowings. As of June 30, 2018, we had an accumulated deficit of $375.8 million. Our net loss was $18.3 million and $41.1 million for the six months ended June 30, 2018 and 2017, respectively. Our ability to become and remain profitable depends on our ability to generate revenue or sales. We do not expect to generate significant revenue or sales unless and until we or a collaborator obtain marketing approval for and commercialize oliceridine, TRV250 or TRV734.

In September 2014, we announced we had entered into a senior secured tranched term loan credit facility with Oxford Finance LLC and Pacific Western Bank (formerly Square 1 Bank), of which $22.2 million remains outstanding as of June 30, 2018. As of January 1, 2018, we began making monthly payments of both principal and interest, which will be required until the loan maturity of March 1, 2020.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, seek regulatory approval for, and prepare for commercialization of our product candidates and repay our outstanding loan obligations. If we obtain regulatory approval for oliceridine, we expect to incur significant expenses associated with the launch of this product. We will need to obtain substantial additional funding in connection with our continuing operations. We will seek to fund our operations through the sale of equity, debt financings or other sources, including potential collaborations. However, we may be unable to raise additional funds or enter into such other agreements when needed on favorable terms, or at all. If we fail to raise capital or enter into such other arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue our operations, development programs, and/or any future commercialization efforts.

Senior Secured Tranched Term Loan Credit Facility

In September 2014, we entered into a loan and security agreement with Oxford Finance LLC and Pacific Western Bank, or the lenders, pursuant to which they agreed to lend us up to $35 million in a three-tranche series of term loans (Term Loans A, B, and C). Upon initially entering into the agreement, we borrowed $2 million under Term Loan A. On April 13, 2015, we amended the agreement with the lenders to change the draw period for Term Loan B. On December 23, 2015, we further amended the agreement with the lenders to, among other things, change the draw period for Term Loan C, modify the interest only period, and modify the maturity date of the loan. In December 2015, we borrowed the Term Loan B tranche of $16.5 million. Our ability to draw an additional $16.5 million under Term Loan C was subject to the satisfaction of one or more specified triggers related to the results of our Phase 2b clinical trial of TRV027. Although those triggers were not attained, in December 2016, we and the lenders modified the terms and conditions under which we could exercise an option to draw $10 million of Term Loan C. In March 2017, we borrowed the Term Loan C tranche of $10.0 million.

Borrowings under Terms Loans A and B accrue interest at a fixed rate of 6.50% per annum. Borrowings under Term Loan C accrue interest at a fixed rate of 6.98% per annum. We were required to make payments of interest only on borrowings under the loan agreement on a monthly basis through and including January 1, 2018; payments of principal in equal monthly installments and accrued interest began on January 1, 2018 and will continue until the loan matures on March 1, 2020. Upon the last payment date of the amounts borrowed under the agreement, we will be required to pay a final payment fee equal to 6.6% of the aggregate amounts borrowed. In addition, if we repay Term

Loan A, Term Loan B, or Term Loan C prior to the applicable maturity date, we will pay the lenders a prepayment fee of 1.0% of each of Term Loans A and B, and 2.0% of Term Loan C, if the prepayment occurs on or between April 1, 2018 and March 31, 2019, and 1.0% of Term Loan C, if the prepayment occurs on or after April 1, 2019.

Our obligations are secured by a first priority security interest in substantially all of our assets, including our cash and cash equivalents and marketable securities, but excluding our intellectual property (together, the collateral). In addition, we have agreed not to pledge or otherwise encumber our intellectual property, with specified exceptions. Upon an event of default, the lenders have the right to foreclose upon the available collateral, including our existing cash and cash equivalents and marketable securities.

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In connection with entering into the original agreement, we issued to the lenders and placement agent warrants to purchase an aggregate of 7,678 shares of our common stock, of which 5,728 shares remain outstanding as of June 30, 2018. These warrants are exercisable immediately and have an exercise price of $5.8610 per share. The warrants may be exercised on a cashless basis and will terminate on the earlier of September 19, 2024 or the closing of a merger or consolidation transaction in which we are not the surviving entity. In connection with the draw of Term Loan B, we issued to the lenders and placement agent additional warrants to purchase an aggregate of 34,961 shares of our common stock, all of which remain outstanding as of June 30, 2018. These warrants have substantially the same terms as those noted above, and have an exercise price of $10.6190 per share and an expiration date of December 23, 2025. In connection with the draw of Term Loan C, we issued to the lenders and placement agent additional warrants to purchase an aggregate of 62,241 shares of our common stock, all of which remain outstanding as of June 30, 2018. These warrants have substantially the same terms as those noted above, and have an exercise price of $3.6150 per share and an expiration date of March 31, 2027. These detachable warrant instruments have qualified for equity classification and have been allocated upon the relative fair value of the base instrument and the warrants, according to the guidance of ASC 470-20-25-2.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A summary of our significant accounting policies appears in the notes to our audited consolidated financial statements for the year ended December 31, 2017 included in our annual report on Form 10 K. However, we believe that the following accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this discussion.

Stock-Based Compensation

We have applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation — Stock Compensation, or ASC 718, to account for stock-based compensation for employees. We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant.

We have equity incentive plans under which various types of equity-based awards including, but not limited to, incentive stock options, non-qualified stock options, and restricted stock awards, may be granted to employees, non-employee directors, and non-employee consultants. We also have an inducement plan under which various types of equity-based awards, including non-qualified stock options and restricted stock awards, may be granted to new employees.

For stock options granted to employees and directors, we recognize compensation expense for all stock-based awards based on the estimated grant-date fair values. For restricted stock awards to employees, the fair value is based on the closing price of the Company's common stock on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention of paying cash dividends. In connection with the early adoption of ASU 2016-9 in the quarter ended December 31, 2016, we elected an accounting policy to record forfeitures as they occur.

See Note 5, included in Part 1, Item 1 of this quarterly report on Form 10 Q, for a discussion of the assumptions used by the Company in determining the grant date fair value of options granted under the Black Scholes option pricing model, as well as a summary of the stock option activity under the Company’s stock based compensation plan for all years presented.

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Revenue

In accordance with FASB's ASC 606, Revenue from Contracts with Customers, or ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, we performs the following five steps:

(i) identify the contract(s) 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) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when we determine that it is probable we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determines those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in our balance sheet. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date are classified as Current portion of deferred revenue. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as Deferred revenue, net of current portion.

Alliance Revenues

Our revenues have primarily been generated through licensing arrangements. The terms of these arrangements typically include payment to us of one or more of the following: nonrefundable, up-front license fees; regulatory and commercial milestone payments; payments for manufacturing supply services; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our agreements, we perform the following steps:

(i) identification of the promised goods or services in the contract;
(ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
(iii) measurement of the transaction price, including the constraint on variable consideration;
(iv) allocation of the transaction price to the performance obligations; and
(v) recognition of revenue when (or as) the Company satisfies each performance obligation.

See Notes 7 and 8, included in Part 1, Item 1 of this quarterly report on Form 10-Q, for additional details surrounding our licensing arrangements.

We also assess whether there is an option in a contract to acquire additional goods or services. An option gives rise to a performance obligation only if the option provides a material right to the customer that it would not receive

without entering into that contract. Factors that we consider in evaluating whether an option represents a material right include, but are not limited to: (i) the overall objective of the arrangement, (ii) the benefit the collaborator might obtain from the arrangement without exercising the option, (iii) the cost to exercise the option (e.g. priced at a significant and incremental discount) and (iv) the likelihood that the option will be exercised. With respect to options determined to be performance obligations, we recognize revenue when those future goods or services are transferred or when the options expire.

Our revenue arrangements may include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes regulatory or commercial milestone payments, we evaluate whether each milestone is considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of us or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At each reporting period, we assess the probability of achievement of each milestone under our current agreements.

Research and Development Activities: Under our current licensing arrangements, if we are entitled to reimbursement for costs for services we provide, we expect such reimbursement would be an offset to research and development expenses.

Royalties: If we are entitled to receive sales-based royalties from our collaborator, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, provided the reported sales are reliably measurable, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Manufacturing Supply and Research Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee’s discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

We receive payments from our licensees based on schedules established in each contract. Upfront payments are recorded as deferred revenue upon receipt, and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

Recent Accounting Pronouncements

See Note 2, included in Part 1, Item 1 of this quarterly report on Form 10 Q for information on recent accounting pronouncements.

JOBS Act

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, contains provisions that, among other things, reduce reporting requirements for an “emerging growth company.” As an emerging growth company, we have elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new

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or revised accounting standards and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

Results of Operations

Comparison of the three and six months ended June 30, 2018 and 2017 (in thousands)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	Change	2018	2017	Change
Revenue	$ 2,500	$ —	$ 2,500	$ 2,500	$ —	$ 2,500
Operating expenses:						
General and administrative	5,926	4,385	1,541	10,998	9,264	1,734
Research and development	5,128	15,499	(10,371)	9,726	31,595	(21,869)
Restructuring	41	—	41	64	—	64
Total operating expenses	11,095	19,884	(8,789)	20,788	40,859	(20,071)
Loss from operations	(8,595)	(19,884)	11,289	(18,288)	(40,859)	22,571
Other income (expense):						
Change in fair value of warrant liability	4	19	(15)	4	56	(52)
Net gain (loss) on asset disposals	(107)	1	(108)	116	1	115
Miscellaneous income	500	—	500	1,428	628	800
Interest income	226	163	63	425	337	88
Interest expense	(597)	(731)	134	(1,275)	(1,309)	34
Gain on foreign currency exchange	10	—	10	10	—	10
Total other income	36	(548)	584	708	(287)	995
Loss before income tax expense	(8,559)	(20,432)	11,873	(17,580)	(41,146)	23,566
Foreign income tax expense	(745)	—	(745)	(745)	—	(745)
Net loss attributable to common stockholders	$ (9,304)	$ (20,432)	$ 11,128	$ (18,325)	$ (41,146)	$ 22,821

Revenue

The revenue recognized primarily relates to the upfront payments received at inception of the agreements.

General and administrative expense

General and administrative expenses consist principally of salaries and related costs for personnel in our executive, finance, commercial, and other administrative areas, including stock based compensation and travel expenses. Other general and administrative expenses include professional fees for legal, market research, consulting, and accounting services.

General and administrative expenses increased by $1.5 million and $1.7 million, or 35% and 19%, for the three and six months ended June 30, 2018, respectively, as compared to the same periods in 2017, primarily related to employee separation payments, an increase in market research expenditures associated with launch readiness, and increased rent and related expenditures associated with the relocation of our corporate headquarters to Chesterbrook, Pennsylvania in July 2017.

Research and development expense

Research and development expenses consist primarily of costs incurred for research and the development of our product candidates. In addition, research and development expenses include salaries and related costs for our research and development personnel and stock-based compensation expense and travel expenses for such individuals.

Research and development costs are expensed as incurred and are tracked by discovery program and subsequently by product candidate once a product candidate has been selected for development. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

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In October 2017, we announced a restructuring and reduction in force of 21 employees, primarily in the research and development area, as well as other cost saving initiatives.

Research and development expenses decreased by $10.4 million and $21.9 million, or 67% and 69%, for the three and six months ended June 30, 2018, respectively, as compared to the same periods in 2017. The following table summarizes our research and development expenses (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Personnel-related costs	$ 2,132	$ 3,478	$ 4,409	$ 7,174
Oliceridine	2,050	9,670	3,428	20,426
TRV027	6	20	33	113
TRV250	775	898	1,471	1,341
Other research and development	165	1,433	404	2,541
	$ 5,128	$ 15,499	$ 9,745	$ 31,595

The decrease in research and development expenses in 2018 was primarily attributable to the completion of the oliceridine Phase 3 clinical program in 2017, and to a decrease in expenditures resulting from the October 2017 restructuring and reduction in force and associated decrease in research and laboratory-related costs.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through private placements and public offerings of our equity securities, debt borrowings and payments received under collaboration agreements. At June 30, 2018, we had an accumulated deficit of $375.8 million, working capital of $47.5 million, cash and cash equivalents of $24.0 million, restricted cash of $1.4 million, and marketable securities of $39.5 million.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2018 and 2017 (in thousands):

	Six Months Ended June 30,	
	2018	2017
Net cash (used in) provided by:		
Operating activities	$ (15,743)	$ (47,748)
Investing activities	9,981	13,778
Financing activities	13,242	23,960
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 7,480	$ (10,010)

Net cash used in operating activities

Net cash used in operating activities was $15.7 million for the six months ended June 30, 2018 and consisted primarily of a net loss of $18.3 million and changes in operating assets and liabilities. Changes in prepaid expenses and other assets, accounts payable and accrued expenses result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations. Deferred revenue relates to our ex-U.S. licensing activities in China.

Net cash used in operating activities was $47.7 million for the six months ended June 30, 2017 and consisted primarily of a net loss of $41.1 million and a decrease in accounts payable and accrued expenses of $9.6 million, primarily associated with the completion of the Phase 3 APOLLO-1 and APOLLO-2 studies of oliceridine. Changes in accounts payable and accrued expenses result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

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Net cash used in investing activities

Net cash used in investing activities was $10.0 million for the six months ended June 30, 2018 and $13.8 million for the six months ended June 30, 2017. Investing activities in both periods consisted primarily of purchases and maturities of marketable securities.

Net cash provided by financing activities

Net cash provided by financing activities was $13.2 million for the six months ended June 30, 2018, which was primarily due to net proceeds of $19.5 million from the sale of common stock through our at-the-market, or ATM, sales facility with Cowen and Company, LLC, or Cowen, offset by principal repayments on our Term Loans of $6.3 million.

Net cash provided by financing activities was $24.0 million for the six months ended June 30, 2017, which was primarily due to net proceeds of $9.9 million from the March 31, 2017 draw of Term Loan C and net proceeds of $13.7 million from the sale of common stock through our ATM sales facility with Cowen.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses and negative cash flows from operations for the foreseeable future. We expect our cash expenditures to continue to be significant in the near term as we prepare for future regulatory activities, and continue clinical development of TRV250. Additionally, over the next twelve months, we anticipate that our payroll and other general and administrative expenses will increase as we prepare for commercial operations, particularly with respect to expenses associated with the selling and marketing of oliceridine, if approved by the FDA.

We believe that our cash and cash equivalents and marketable securities as of June 30, 2018, together with interest thereon, as well as proceeds from the sale of shares of common stock under our $50 million ATM sales facility with Cowen, and from ex-U.S. licensing activities in China between June 30, 2018 and the date of this filing, to be sufficient to fund our operating expenses and capital expenditure requirements for at least twelve months following the date of this filing. If approved by FDA on November 2, 2018, and following DEA Scheduling, we expect to launch oliceridine in the United States in the first half of 2019. The extent of our commercial efforts for oliceridine, including the number of sales representatives and medical science liaisons at launch, will depend to a significant extent on the success of our fundraising efforts between the date of this filing and the launch date. In all cases, we anticipate that we will need to raise substantial additional financing in the future to fund our operations. To meet these requirements, we may seek to sell equity or convertible securities in public or private transactions that may result in dilution to our stockholders. In June 2018, we filed a $175 million shelf registration statement that includes a $50 million ATM sales facility with Cowen acting as our sales agent. As of June 30, 2018, the entire $50 million remained available under the ATM sales facility. We may offer and sell shares of our common stock under the existing registration statement (including under our ATM facility) or any registration statement we may file in the future. If we raise additional funds through the issuance of convertible securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations.

Ultimately, there can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our future capital requirements will depend on many factors, including:

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the costs, timing and outcome of regulatory review of the oliceridine NDA or any future product candidates, both in the United States and in territories outside the United States;

- the costs, timing, and extent of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;

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- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the number and development requirements of any other product candidates that we may pursue;
- our ability to enter into collaborative agreements for the development and/or commercialization of our product candidates, including for oliceridine;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims, both in the United States and in territories outside the United States.

Please see “Risk Factors” section of this Quarterly Report, for additional risks associated with our substantial capital requirements.

Contractual Obligations and Commitments

The following is a summary of our long-term contractual cash obligations as of June 30, 2018 (in thousands):

	Payments Due By Period				
	Total	Less than 1 Year	1 – 3 years	3 – 5 years	More than 5 years
Operating lease obligations(1)	$ 13,633	$ 824	$ 2,704	$ 2,802	$ 7,303
Loans payable	24,048	12,667	11,381	—	—
Purchase Obligations	2,312	2,312	—	—	—
Total	$ 39,993	$ 15,803	$ 14,085	$ 2,802	$ 7,303

(1) Operating lease obligations reflect our obligation to make payments in connection with the leases for our office spaces, including our current location in Chesterbrook, Pennsylvania and our previous location in King of Prussia, Pennsylvania.

Other Commitments

In addition, in the course of normal business operations, we have agreements with contract service providers to assist in the performance of our research and development and manufacturing activities. We can elect to discontinue the work under these agreements at any time. We also could enter into additional collaborative research, contract research, manufacturing and supplier agreements in the future, which may require upfront payments and even long-term commitments of cash.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reported period. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Please see the "Critical Accounting Policies and Significant Judgments and Estimates" section of our most recent Annual Report on Form 10 K as filed with the SEC which is incorporated herein by reference, for full detail. Except for the added disclosures related to Alliance revenue in Note 2, included in Part 1, Item 1 of this quarterly report

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on Form 10 Q, we did not make any significant changes to our critical accounting policies during the six months ended June 30, 2018.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable SEC regulations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations.

We had cash and cash equivalents of $24.0 million and marketable securities of $39.5 million at June 30, 2018, consisting primarily of funds in cash, money market funds, U.S. Treasury and U.S. government agency securities. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10% increase or decrease in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Interim Principal Financial Officer

and Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2018, the end of the period covered by this Quarterly Report on Form 10 Q.

Based on our evaluation, we believe that our disclosure controls and procedures as of the date of our Quarterly Report on Form 10 Q have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. We believe that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. As a result, it is possible that, had our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, material weaknesses and significant control deficiencies may have been identified. However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II

ITEM 1. LEGAL PROCEEDINGS

The Company is not involved in any legal proceeding that it expects to have a material effect on its business, financial condition, results of operations and cash flows.

ITEM 1A. RISK FACTORS

Our business is subject to numerous risks. You should carefully consider the following risks and all other information contained in this Quarterly Report on Form 10-Q, as well as general economic and business risks, together with any other documents we file with the SEC. If any of the following events actually occur or risks actually materialize, it could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $18.3 million for the six months ended June 30, 2018, and $71.9 million, $103.0 million, and $50.5 million for the years ended December 31, 2017, 2016, and 2015, respectively. As of June 30, 2018, we had an accumulated deficit of $375.8 million. To date, we have financed our operations primarily through private placements and public offerings of our equity securities and debt borrowings. We have devoted substantially all of our financial resources and efforts to research and development, including nonclinical studies and clinical trials. We still have not completed development of any of our product candidates. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase as we:

- establish sales, marketing and distribution capabilities and scale up external manufacturing capabilities to commercialize oliceridine, if approved, and any other products that we choose not to license to a third party and for which we may obtain regulatory approval;
- conduct clinical trials for TRV250, our receptor product candidate, as well as any additional clinical trials of oliceridine that may be required by FDA;
- seek to identify additional product candidates;
- conduct clinical trials and seek regulatory approvals for any product candidates that successfully complete clinical trials;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional sales, marketing, medical, clinical and scientific personnel; and

add operational, financial, and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

To become and remain profitable, we must succeed in raising substantial additional funding for the Company and developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing nonclinical testing and clinical trials of our product candidates, identifying additional product candidates, potentially entering into collaboration and license agreements, obtaining regulatory approval for product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities and have not begun others. We may never succeed in these activities and, even if we do, may never achieve profitability.

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Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses, whether we will have sufficient funding available to or when, or if, we will be able to achieve profitability. If we are required by the FDA or foreign regulatory authorities, to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials, making necessary regulatory filings, or the development of any of our product candidates, our expenses could increase. During the first half of 2019, assuming FDA approval on November 2, 2018 and Drug Enforcement Administration, or DEA, scheduling, we expect to launch oliceridine in the United States. The extent of our commercial efforts for oliceridine, including the number of sales representatives and medical science liaisons at launch, will depend to a significant extent on the success of our fundraising efforts between the date of this filing and the launch date. Absent substantial additional fundraising, the level and extent of our commercial efforts may lead to a delay in our ability to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, continue our development efforts, diversify our product offerings, or even continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We will need substantial additional funding, which may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Over the next several years, we expect to incur significant expenses in connection with our current operations and the servicing and repayment of our outstanding debt obligations. In preparation for the potential regulatory approval of oliceridine, we expect to incur significant expenses related to our product manufacturing, marketing, sales, and distribution efforts. Accordingly, we will need to obtain substantial additional funding for these efforts and for the continued repayment of our outstanding term loans through the March 2020 maturity date; we would seek to obtain this funding through the sale of equity, debt financings, and/or other sources, including potential collaborations. Ultimately, we may be unable to raise additional funds or enter into such other arrangements when needed, on favorable terms, or at all. If we fail to raise additional capital or enter into such arrangements as, and when, needed, we could be forced to:

- significantly delay, scale back, or discontinue our operations, development programs, and/or any future commercialization efforts;
- relinquish, or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves;
- seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- cease operations altogether.

We estimate that our existing cash and cash equivalents and marketable securities as of June 30, 2018, together with interest thereon, as well as proceeds from the sale of shares of common stock under the Company's at the market, or

ATM, sales agreement with Cowen and Company, LLC, or Cowen, and from ex-U.S. licensing activities in China between June 30, 2018 and the date of this filing to be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months following the date of this filing. If we are unable to raise additional funds prior to this date, or we do not take steps to reduce our expenses, our lenders may conclude that there has been a material adverse change in the Company's financial condition, or a material impairment in the value of the loan collateral or in the prospect of repayment of our obligations to the lenders. In this case, the lenders have the right to foreclose on the available collateral, including our cash and cash equivalents and marketable securities.

The extent of our future capital requirements will depend on many factors, including:

- the costs, timing, and outcome of regulatory review of the oliceridine NDA or any future product candidates, both in the United States and in territories outside the United States;

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- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the scope, progress, results and costs of nonclinical development, laboratory testing, and clinical trials for our other product candidates, including TRV250;
- the number and development requirements of other product candidates that we pursue;
- our ability to enter into collaborative agreements for the development and commercialization of our product candidates, including oliceridine;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel; and
- the costs involved in preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, both in the United States and in territories outside the United States.

Identifying potential product candidates and conducting nonclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. Despite these efforts, we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success or meet our expectations. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available until, at the earliest, the first half of 2019, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenue and positive cash flows from operations, we expect to finance our cash needs through a combination of equity offerings, debt financings, and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, either at the time of such capital raise or thereafter, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Preferred equity financing and additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced active operations in late 2007, and our activities to date have been limited to, among other things, organizing and staffing our company, business planning, raising capital, developing our product platform, identifying potential product candidates, undertaking nonclinical studies, and conducting clinical trials. With the exception of oliceridine, our product candidates are early in development. We have not yet demonstrated our ability to obtain regulatory approvals, manufacture a product at commercial scale or arrange for a third party to do so on our behalf, or conduct sales, marketing, and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as reliable as they could be if we had a longer operating history.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to significantly expand our capabilities to support future activities related to the approval, manufacture, and commercialization of our product candidates. We may be unsuccessful in adding such capabilities.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past quarterly or annual periods as indications of future operating performance.

Risks Related to Regulatory Approval of Our Product Candidates

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to timely commercialize, or to commercialize at all, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for our product candidates will prevent us from commercializing these product candidates and will significantly limit our ability to generate revenue in the future. To date, we have not received approvals to market any of our product candidates from regulatory authorities in any jurisdiction and we may never be successful in obtaining any such approvals.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals, and we have relied and expect to continue to rely on third parties to assist us in this process. Securing marketing approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product. The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For oliceridine, we have submitted an NDA to the FDA. The FDA has indicated to us that the Prescription Drug User Fee Act review date for the NDA is November 2, 2018. It is possible that FDA may not meet this target date for any number of reasons, including if it considers the submission of additional information or data during the review process to constitute a major amendment to the NDA. Ultimately, the oliceridine NDA may not be approved by or on the November 2, 2018 target date, if at all.

The FDA also has indicated to us that it expects to convene an Advisory Committee as part of the review process, which we currently expect will be held in October 2018. The Advisory Committee will discuss and advise FDA on the risk-benefit profile of oliceridine. In advance of this Advisory Committee meeting, we and the FDA will submit briefing documents for the committee’s review, and these briefing documents will be made available to the public and may include information from the oliceridine development program that have not previously been disclosed. Historically, for some companies, disclosure of information in this manner has led to increased volatility in their stock

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price. The Advisory Committee and FDA may interpret nonclinical and clinical data differently than we and our experts have or conclude that there is not sufficient nonclinical and/or clinical data to support approval of our NDA. Across the Phase 3 clinical development program for oliceridine, there were three Suspected Unexpected Serious Adverse Reactions, or SUSARs, reported to the FDA: one each for instances of post-operative ileus and lethargy, and one patient who experienced hepato-renal failure. All cases resolved without clinical sequelae. While we believe these events are consistent with the presumed mechanism of action of oliceridine or with the clinical context of the surgical patient population included in the Phase 3 study program, the Advisory Committee and FDA may disagree with our interpretations and conclusions. Furthermore, press coverage and public scrutiny of the materials that will be discussed at the Advisory Committee meeting may negatively affect the potential for our NDA to receive approval, particularly in light of the current nationwide focus on opioids. Even if we ultimately obtain approval of the NDA, the matters discussed at the Advisory Committee meeting could limit our ability to successfully commercialize oliceridine.

The feedback received from an Advisory Committee can have a substantial impact on the FDA's decision to approve or reject an NDA. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical studies or clinical trials, among other things. In addition, varying interpretations of the data obtained from nonclinical and clinical testing, including from our ATHENA Phase 3 open label safety study, QTc interval study, renal impairment study, or other Phase 1, 2 or 3 clinical studies, could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post approval commitments that render the approved product not commercially viable.

We have submitted to the FDA a proposed proprietary name for oliceridine and we are awaiting feedback. FDA will only approve a tradename, if at all, when approving the NDA. If we experience delays in obtaining approval of our NDA, the commercial prospects for our product candidates may be harmed and our ability to generate revenue may be materially impaired. Furthermore, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications, dosages, or presentations than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate or that includes language, such as a black box warning, that may impair our ability to successfully commercial that product candidate. Any of these scenarios could negatively impact the commercial prospects for our product candidates or our ability to raise sufficient capital to support our operations in the future.

Our μ opioid receptor targeted product candidates, including oliceridine, may require Risk Evaluation and Mitigation Strategies, which could delay the approval of these product candidates and increase the cost, burden and liability associated with the commercialization of these product candidates.

Risk Evaluation and Mitigation Strategy, or REMS, are imposed by FDA to assure safe use of the product candidates, either as a condition of product candidate approval or on the basis of new safety information. Our μ opioid receptor product candidates, including oliceridine, if approved, may require a REMS, and it is possible that our other product candidates may require a REMS. The REMS may include medication guides for patients, special communication plans to health care professionals or elements to assure safe use such as restricted distribution methods, patient registries and/or other risk minimization tools. We cannot predict the specific REMS that may be required as part of the FDA's approval of our product candidates. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of our product candidates, if approved. Depending on the extent of the REMS requirements, these requirements may significantly increase our costs to commercialize these product candidates and could negatively affect sales. Furthermore, risks of our product candidates that are not adequately addressed through proposed REMS for such product candidates also may prevent or delay their approval for commercialization.

Our µ opioid receptor targeted product candidates, including oliceridine, are expected to be classified as controlled substances, the making, use, sale, importation, exportation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies.

Our µ opioid receptor targeted product candidates, including oliceridine, are likely to be classified as controlled substances, which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Controlled substances are regulated under the Federal Controlled Substances Act of 1970, or CSA, and regulations of the DEA.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. We expect oliceridine to be regulated by the DEA as a Schedule II controlled substance.

Various states also independently regulate controlled substances. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For any of our product candidates classified as controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in clinical trials for our product candidates, and, in the future, the ability to produce and distribute our products in the volume needed to both meet commercial demand and build inventory to mitigate possible supply disruptions.

Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates including controlled substances. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our product candidates that are classified as controlled substances.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

To market and sell our products in the European Union, Asia, and many other jurisdictions, we, our current collaborators in South Korea and China for oliceridine, or any future third party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

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Any product candidate for which we obtain marketing approval could be subject to post marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post marketing information and reports, registration, and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The FDA also may impose requirements for costly post marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off label use and if we do not market our products for only their approved indications, we may be subject to enforcement action for off label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing

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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.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third party payors, and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third party payors, and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- our ability to offer the product for sale profitably and at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the level and extent of sales, marketing, and distribution support;
- the availability of third party coverage and adequate reimbursement;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved; and
- any restrictions on the use of our products, both on their own and together with other medications.

If we are unable to establish manufacturing, sales, marketing, and distribution capabilities or to enter into agreements with third parties to produce, market, sell, and distribute our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We currently have limited resources focused on the manufacturing, marketing, sales, and distribution of pharmaceutical products and have limited experience and capabilities in this area. To commercialize any product candidates that receive marketing approval, we would need to build manufacturing, marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If we successfully develop and obtain regulatory approval for any of our product candidates, we expect to build or outsource a targeted specialist sales force to market or co-promote the product in the United States; we currently do not expect to build sales, manufacturing and distribution capabilities outside of the United States, although this expectation could change in the future. There are substantial risks involved with establishing sales, marketing, and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred certain commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

There are a number of factors that may inhibit our efforts to commercialize our products on our own, including:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel or to outsource these tasks to a third party;

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- the inability of sales personnel to obtain access to physicians or other relevant personnel or educate adequate numbers of physicians or others on the benefit of our future products;
- the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating a sales and marketing organization.

As an alternative to establishing our own sales force, we may choose to partner with third parties that have well-established direct sales forces to sell, market and distribute our products, particularly in markets outside of the United States. If we are unable to enter into collaborations with third parties for the commercialization of approved products, if any, on acceptable terms or at all, or if any such partner does not devote sufficient resources to the commercialization of our product or otherwise fails in commercialization efforts, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval.

For oliceridine, we will need to partner with one or more third parties to sell, market and distribute this product, if approved, outside the United States. In April 2018 and May 2018, we entered into exclusive licensing agreements for the development and commercialization of oliceridine in South Korea and China, respectively. Such partnerships in South Korea and China may not be successful, and we may be unsuccessful in our efforts to secure additional partnerships outside the United States.

We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. In addition to existing therapeutic treatments for the indications we are targeting with our product candidates, if any of our product candidates achieves regulatory approval, we also face potential competition from other drug candidates in development by other companies. Oliceridine also may compete against, or be used in combination with, OFIRMEV® (IV acetaminophen), marketed by Mallinckrodt plc, with EXPAREL® (liposomal bupivacaine), marketed by Pacira Pharmaceuticals, Inc., CALDOLOR® (IV ibuprofen), marketed by Cumberland Pharmaceuticals, DYLOJECT™ (IV diclofenac), and marketed by Hospira. In addition to currently marketed IV analgesics, we are aware of a number of products in development that are aimed at improving the treatment of moderate-to-severe acute pain. AcelRx Pharmaceuticals, Inc. is developing a range of acute pain products involving sufentanil oral nanotabs in hand held dispensers including DSUVIA™ and ZALVISO™. Innocoll Holdings plc, and Heron Therapeutics Inc. have proprietary long acting reformulations of bupivacaine in development. Recro Pharma, Inc. is developing an IV version of the NSAID meloxicam. Cara Therapeutics Inc. is developing IV and oral dose forms of a peripherally restricted opioid receptor agonist, which has been administered in combination with µ opioids in clinical trials. Avenue Therapeutics, Inc. is developing an IV version of the generic opioid tramadol for moderate-to-severe acute pain. Some of these potential competitive compounds are being developed by large, well-financed, and experienced pharmaceutical and biotechnology companies, or have been partnered with such companies, which may give them development, regulatory and marketing advantages over us.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third party payors seeking to encourage the use of generic products. Generic products are currently on the market for the indications that we are pursuing. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competing generic products.

Some of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise than we do in research and development, manufacturing, nonclinical testing, conducting clinical trials, obtaining regulatory approvals, and selling and marketing approved products. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies also may prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we or any future collaborators are able to commercialize any of our product candidates, the product candidates may become subject to unfavorable pricing regulations, third party coverage and reimbursement policies, healthcare reform initiatives, or regulatory or political concerns.

Both our and our collaborators' ability to commercialize any of our product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government payor programs at the federal and state level, including Medicare and Medicaid, private health insurers, managed care plans and other organizations. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. In addition, for hospital products, a private health insurer or Medicare will typically reimburse a fixed fee for certain procedures, including in patient surgeries. Pharmaceutical products such as oliceridine, if approved, that may be used in connection with the surgery generally will not be separately reimbursed and, therefore, a hospital would have to assess the cost of oliceridine, if approved, relative to its benefits. Current or future efforts to limit the level of reimbursement for in patient hospital procedures could cause a hospital to decide not to use oliceridine, if approved by the FDA. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications or procedures. Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any drug that we or our collaborators commercialize and, even if these are available, the level of reimbursement for a product or procedure may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of, any product candidate for which we or our collaborators obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to seek to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we or our collaborators may not be able to successfully commercialize any product candidates for which marketing approval is obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or analogous regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution expenses. Interim reimbursement levels for new drugs, if applicable, also may not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our or our collaborators' inability to promptly obtain coverage and adequate reimbursement rates from both government funded and private payors for any approved drugs that we develop could adversely affect our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our collaborators might obtain marketing approval for a drug in a particular country, but then be subject to price regulations that delay commercial launch of the drug, possibly for lengthy time periods, and negatively impact our ability to generate revenue from the sale