TREVENA INC
Form 10-Q
November 08, 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 September 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	26-1469215
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
955 Chesterbrook Boulevard, Suite 110 Chesterbrook, PA	19087
(Address of Principal Executive Offices)	(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 every Interactive Data File required to be submitted 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 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	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 November 2, 2018: 82,323,413

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 ability to fund future operating expenses and capital expenditures with our current cash resources or to secure additional funding in the future;
- our plans to develop and potentially commercialize our product candidates;
- our planned nonclinical studies and clinical trials for our product candidates;
- the extent of clinical trials potentially required by the FDA for our product candidates;
- the timing and likelihood of obtaining and maintaining regulatory approvals for our product candidates, including as a result of the complete response letter received for oliceridine;
- 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

· 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)

	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 24,339	$ 16,557
Marketable securities	45,700	49,543
Prepaid expenses and other current assets	1,196	1,393
Total current assets	71,235	67,493
Restricted cash	1,301	1,413
Property and equipment, net	3,565	3,805
Intangible asset, net	10	11
Total assets	$ 76,111	$ 72,722
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 836	$ 1,424
Accrued expenses and other current liabilities	3,221	4,303
Current portion of loans payable, net	12,528	12,425
Deferred rent	—	61
Total current liabilities	16,585	18,213
Loans payable, net	7,853	15,725
Capital leases, net of current portion	23	31
Deferred rent, net of current portion	2,993	3,006
Warrant liability	13	10
Other long-term liabilities	—	1,104
Total liabilities	27,467	38,089
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock-$0.001 par value; 200,000,000 and 100,000,000 shares authorized September 30, 2018 and December 31, 2017, respectively; 82,323,291 and 62,310,795 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	82	62
Preferred stock-$0.001 par value; 5,000,000 shares authorized, none issued or outstanding at September 30, 2018 and December 31, 2017	—	—
Additional paid-in capital	428,880	392,103
Accumulated deficit	(380,298)	(357,490)
Accumulated other comprehensive loss	(20)	(42)
Total stockholders equity'	48,644	34,633
Total liabilities and stockholders' equity	$ 76,111	$ 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Alliance revenue	$ 3,000	$ —	$ 5,500	$ —
Operating expenses:				
General and administrative	3,908	5,232	14,906	14,496
Research and development	3,350	10,181	13,076	41,776
Restructuring charges	—	—	64	—
Total operating expenses	7,258	15,413	28,046	56,272
Loss from operations	(4,258)	(15,413)	(22,546)	(56,272)
Other income (expense):				
Change in fair value of warrant liability	(7)	(2)	(3)	53
Net gain on asset disposals	32	—	148	1
Miscellaneous income	—	—	1,428	628
Interest income	268	167	693	505
Interest expense	(515)	(732)	(1,790)	(2,041)
Gain (loss) on foreign currency exchange	(3)	(19)	7	(19)
Total other income (expense)	(225)	(586)	483	(873)
Loss before income tax expense	(4,483)	(15,999)	(22,063)	(57,145)
Foreign income tax expense	—	—	(745)	—
Net loss attributable to common stockholders	$ (4,483)	$ (15,999)	$ (22,808)	$ (57,145)
Other comprehensive gain (loss), net:				
Unrealized gain (loss) on marketable securities	—	36	22	(23)
Other comprehensive gain (loss), net	—	36	22	(23)
Comprehensive loss	$ (4,483)	$ (15,963)	$ (22,786)	$ (57,168)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.06)	$ (0.27)	$ (0.32)	$ (0.98)
Weighted average common shares outstanding, basic and diluted	77,445,675	60,113,327	70,604,827	58,475,079

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 September 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	—	—	3,519	—	—	3,519
Exercise of stock options	132,952	—	83	—	—	83
Issuance of common stock, net of issuance costs	19,879,544	20	33,175	—	—	33,195
Unrealized gain on marketable securities	—	—	—	—	22	22
Net loss	—	—	—	(22,808)	—	(22,808)
Balance, September 30, 2018	82,323,291	$ 82	$ 428,880	$ (380,298)	$ (20)	$ 48,644

See accompanying notes to financial statements.

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TREVENA, INC.

Statements of Cash Flows (Unaudited)

(in thousands)

	Nine Months Ended September 30, 2018	2017
Operating activities:		
Net loss	$ (22,808)	$ (57,145)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	496	345
Stock-based compensation	3,519	5,344
Noncash interest expense on loans	626	786
Loss on disposal of assets	124	—
Revaluation of warrant liability	3	(53)
Amortization (accretion) of bond premium (discount) on marketable securities	(88)	415
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	197	(324)
Accounts payable, accrued expenses and other liabilities	(1,744)	(8,816)
Net cash used in operating activities	(19,675)	(59,448)
Investing activities:		
Purchases of property and equipment	(379)	(3,391)
Maturities of marketable securities	50,284	72,123
Purchases of marketable securities	(46,330)	(44,730)
Net cash provided by investing activities	3,575	24,002
Financing activities:		
Proceeds from exercise of common stock options	83	355
Proceeds from issuance of common stock, net	33,195	19,197
Capital lease payments	(8)	(5)
Proceeds from loans payable, net	—	9,921
Repayments of loans payable, net	(9,500)	—
Net cash provided by financing activities	23,770	29,468
Net increase (decrease) in cash and cash equivalents	7,670	(5,978)
Cash, cash equivalents and restricted cash—beginning of period	17,970	25,459
Cash, cash equivalents and restricted cash—end of period	$ 25,640	$ 19,481
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,161	$ 1,253
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

September 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 focused on the development and commercialization of new and innovative treatment options for patients in pain. 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. On November 2, 2018, the U.S. Food and Drug Administration, or FDA, issued a complete response letter, or CRL, with respect to the Company’s new drug application, or NDA, for oliceridine. In the CRL, the FDA requested additional clinical data on QT prolongation and indicated that the submitted safety database is not of adequate size for the proposed labeling. The FDA also requested certain additional nonclinical data and validation reports. The Company plans to schedule a meeting with the FDA to discuss the items identified in the CRL. On November 8, 2018, the Company announced a restructuring of its workforce. See Note 12 for additional information.

Since its inception, the Company has incurred losses and negative cash flows from operations. At September 30, 2018, the Company had an accumulated deficit of $380.3 million. The Company’s net loss was $22.8 million and $57.1 million for the nine months ended September 30, 2018 and 2017, respectively. The Company expects its cash and cash equivalents of $24.3 million and marketable securities of $45.7 million as of September 30, 2018, together with interest thereon, to be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months following the date of this filing.

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 September 30, 2018, its results of operations and its comprehensive loss for the three and nine months ended September 30, 2018 and 2017, its statement of stockholders’ equity for the period from January 1, 2018 to September 30, 2018, and its cash flows for the nine months ended September 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 nine months ended September 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

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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 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.

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

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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 nine months ended September 30, 2018, the Company recorded foreign income tax expense related to withholdings associated with our ex-U.S. licensing activities. For the nine months ended September 30, 2017, the Company recorded no tax expense or benefit due to the expected 2017 loss and its historical losses. The Company has not recorded its net deferred tax asset as of either September 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 likely that the Company will not realize these future tax benefits. As of September 30, 2018 and December 31, 2017, the Company had no uncertain tax positions.

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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 September 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 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 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 TCJA (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 TCJA 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 in the process of evaluating the effect this standard will have on its financial statements and related disclosures. For additional information on the Company's Chesterbrook office lease, please see our Contractual Obligations and Commitments table included in Item 2 of this Form 10 Q, which reflects total cash basis operating lease obligations of $13.4 million and does not include the impact of any future sublease revenue. See Note 12 for additional information.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement. The new guidance modifies the disclosure requirements related to fair value measurements in Topic 820, Fair Value Measurement, including removing certain previous disclosure requirements, adding certain new disclosure requirements, and modifying certain other disclosure requirements. The ASU will be effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. 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 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 September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018						
	Adjusted Cost	Unrealized Gains	Unrealized Loss	Fair Value	Cash and Cash Equivalents	Restricted Cash	Marketable Securities
Cash	$ 14,905	$ —	$ —	$ 14,905	$ 13,604	$ 1,301	$ —
Level 1 (1):							
Money market funds	10,735	—	—	10,735	10,735	—	—
U.S. treasury securities	18,385	—	(10)	18,375	—	—	18,375
Subtotal	29,120	—	(10)	29,110	10,735	—	18,375
Level 2 (2):							
U.S. government agency securities	27,335	—	(10)	27,325	—	—	27,325
Total	$ 71,360	$ —	$ (20)	$ 71,340	$ 24,339	$ 1,301	$ 45,700

	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 September 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 nine months ended September 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 nine months ended September 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 on 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 September 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 September 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 outstanding at September 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 September 30, 2018, borrowings of $19.0 million attributable to Term Loans A, B, and C remain outstanding. Interest expense of $1.2 million and $1.3 million was recorded during the nine months ended September 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 03, 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 nine months ended September 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 September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Gross proceeds	$ 19,000	$ 28,500
Debt discount and debt issuance costs (1)	1,381	(350)
Carrying value	20,381	28,150
Current portion of loans payable, net	12,528	12,425
Loans payable, net	$ 7,853	$ 15,725

(1) 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 September 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, or the Prior ATM Agreement, with Cowen and Company, LLC, or 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 $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 nine months ended September 30, 2018, the Company issued and sold 11,388,037 shares of common stock under the Prior ATM Agreement at a weighted average price per share of $1.80. The net offering proceeds to the Company in 2018 for sales under the Prior ATM were approximately $20.0 million after deducting related expenses, including commissions. Sales of common stock under 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 September 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 third quarter of 2018, 8,491,507 shares were sold under this ATM sales agreement at a weighted average price per share of $1.60. The net offering proceeds to the Company were approximately $13.2 million after deducting related expenses, including commissions. As of September 30, 2018, there was approximately $36.4 million of available capacity under this ATM facility.

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

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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.

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$ 208	$ 533	$ 952	$ 1,974
General and administrative	526	1,124	2,567	3,370
Total stock-based compensation	$ 734	$ 1,657	$ 3,519	$ 5,344

	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	3,191,375	1.79	
Exercised	(132,952)	0.63	
Forfeited/Cancelled	(3,106,588)	4.82	
Balance, September 30, 2018	8,576,058	$ 4.15	7.80
Vested or expected to vest at September 30, 2018	8,576,058	$ 4.15	7.80
Exercisable at September 30, 2018	3,528,508	$ 5.19	6.30

The intrinsic value of the options exercisable as of September 30, 2018 was $0.4 million, based on the Company's closing stock price of $2.12 per share and a weighted average exercise price of $5.19 per share. At September 30, 2018, there was $8.1 million of total unrecognized compensation expense related to unvested options that will be recognized over the weighted average remaining period of 2.16 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 nine months ended September 30, 2018 and 2017 was estimated at $1.18 and $2.68 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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	Nine Months Ended September 30,	
	2018	2017
Expected term of options (in years)		