TREVENA INC

Form 10-Q

August 03, 2017

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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, 2017

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 (I.R.S. Employer

Incorporation or Organization) Identification No.)

955 Chesterbrook Boulevard, Suite 200

19087

Chesterbrook, PA

(Zip Code)

(Address of Principal Executive Offices)

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," "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

(Do not check if a 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, 2017: 59,696,065

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 and capital expenditures with our current cash resources; our planned clinical trials and preclinical studies for our product candidates;

the timing and likelihood of obtaining and maintaining regulatory approvals for our product candidates;

•he 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 commercialization, 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)

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,037	\$24,266
Marketable securities	70,163	86,335
Prepaid expenses and other current assets	3,462	1,788
Total current assets	87,662	112,389
Property and equipment, net	2,921	1,059
Restricted cash	1,413	1,193
Intangible asset, net	12	13
Total assets	\$ 92,008	\$114,654
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,290	\$8,749
Accrued expenses and other current liabilities	2,822	8,208
Current portion of loans payable, net	7,093	5,039
Deferred rent	56	52
Total current liabilities	12,261	22,048
Loans payable, net	20,895	13,270
Capital leases, net of current portion	15	18
Deferred rent, net of current portion	2,465	187
Warrant liability	19	75
Other long term liabilities	747	475
Total liabilities	36,402	36,073
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock—\$0.001 par value; 100,000,000 shares authorized, 59,456,364 and 55,768,414	<sup>1</sup> 50	56
shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively		30
Preferred stock—\$0.001 par value; 5,000,000 shares authorized, none issued or outstanding at June 30, 2017 and December 31, 2016	_	
Additional paid-in capital	382,375	364,148
Accumulated deficit	•	(285,625)
Accumulated other comprehensive income (loss)		2
Total stockholders' equity	55,606	78,581
Total liabilities and stockholders' equity	\$ 92,008	\$114,654
Total habilities and stockholders equity	ψ 72,000	Ψ117,034

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,		Six Month June 30,	ns Ended
	2017	2016	2017	2016
Revenue:				
Collaboration revenue	_	\$1,875	<b>\$</b> —	\$3,750
Total revenue	_	1,875	_	3,750
Operating expenses:				
General and administrative	4,385	3,697	9,264	7,615
Research and development	15,499	17,203	31,595	32,956
Total operating expenses	19,884	20,900	40,859	40,571
Loss from operations	(19,884)	(19,025)	(40,859)	(36,821)
Other income (expense):				
Change in fair value of warrant liability	19	28	56	70
Net (loss) gain on asset disposals	1		1	
Miscellaneous income	_		628	222
Interest income	163	214	337	407
Interest expense	(731)	(433)	(1,309)	(873)
Total other expense	(548)	(191)	(287)	(174)
Net loss attributable to common stockholders	\$(20,432)	\$(19,216)	\$(41,146)	\$(36,995)
Other comprehensive (loss) income, net:				
Unrealized gain (loss) on marketable securities	(8)	45	(59)	281
Other comprehensive (loss) income	(8)	45	(59)	281
Comprehensive loss	\$(20,440)	\$(19,171)	\$(41,205)	\$(36,714)
Per share information:				
Net loss per share of common stock, basic and diluted	\$(0.35)	\$(0.37)	\$(0.71)	\$(0.71)
Weighted average common shares outstanding, basic and diluted	58,381,86			951,762,467

See accompanying notes to financial statements.

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TREVENA, INC.

Statement of Stockholders' Equity (Unaudited)

For the period from January 1, 2017 to June 30, 2017 (in thousands, except share data)

Stockholders' Equity Common Stock

	Number of Shares	Par	Additional Paid-in Capital		Accumulated Other Comprehensi Income (Loss	Total Stockholders' Ve Equity
Balance, January 1, 2017	55,768,414	\$ 56	\$364,148	\$ (285,625)	\$ 2	\$ 78,581
Stock-based compensation expense		_	3,687		_	3,687
Exercise of stock options	283,995	_	355			355
Net issuance of common stock warrant			501	_	_	501
Issuance of common stock, net of issuance costs	3,403,955	3	13,684	_	_	13,687
Unrealized loss on marketable securities			_		(59)	(59)
Net loss		_		(41,146)	_	(41,146)
Balance, June 30, 2017	59,456,364	\$ 59	\$382,375	\$ (326,771)	\$ (57 )	\$ 55,606

See accompanying notes to financial statements.

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# TREVENA, INC.

Statements of Cash Flows (Unaudited) (in thousands)

	Six Months Ended June 30,	
	2017	2016
Operating activities:	2017	2010
Net loss	\$(41.146)	\$(36,995)
Adjustments to reconcile net loss to net cash used in operating activities:	+ ( ! - ) - ! • )	+ (= =,> > = )
Depreciation and amortization	158	119
Stock-based compensation	3,687	2,713
Noncash interest expense on loans	530	271
Revaluation of warrant liability	(56)	(70 )
Amortization of bond premiums on marketable securities	316	804
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,674)	(1,238)
Accounts payable, accrued expenses and other liabilities	(9,563)	(1,090 )
Deferred revenue		(3,750)
Net cash used in operating activities	(47,748)	(39,236)
Investing activities:		
Purchases of property and equipment	(2,019)	(220 )
Maturities of marketable securities	48,443	55,014
Purchases of marketable securities	(32,646)	(37,380)
Net cash provided by investing activities	13,778	17,414
Financing activities:		
Proceeds from exercise of common stock options	355	61
Proceeds from issuance of common stock, net	13,687	11,792
Capital lease payments		(2)
Proceeds from loans payable, net	9,921	_
Net cash provided by financing activities	23,960	11,851
Net decrease in cash and cash equivalents	(10,010)	
Cash, cash equivalents and restricted cash—beginning of period	25,459	46,886
Cash, cash equivalents and restricted cash—end of period	\$15,449	\$36,915
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$778	\$602
Capital lease additions	<b>\$</b> —	9
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, 2017

### 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.

## Liquidity

At June 30, 2017, the Company had an accumulated deficit of \$326.8 million. The Company's net loss was \$41.1 million and \$37.0 million for the six months ended June 30, 2017 and 2016, respectively. The Company expects its cash and cash equivalents of \$14.0 million and marketable securities of \$70.2 million as of June 30, 2017, together with interest thereon, to be sufficient to fund its operating expenses and capital expenditure requirements into the third quarter of 2018.

## 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, 2017, its results of operations and its comprehensive loss for the three and six months ended June 30, 2017 and 2016, its statement of stockholders' equity for the period from January 1, 2017 to June 30, 2017, and its cash flows for the six months ended June 30, 2017 and 2016. 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, 2016. 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 three and six months ended June 30, 2017 and 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2017, any other interim periods, or any future year or period.

### Recent Accounting Standards Not Yet Adopted

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. Early adoption is permitted. 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.

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.

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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, with an option that permits companies to adopt the standard as early as the January 1, 2017. Early application prior to the January 1, 2017 is not permitted. The Company has determined that they will elect the modified retrospective transition method, meaning the cumulative effect of applying the new guidance is recognized at the date of initial application as an adjustment to the opening accumulated deficit balance. Since the Company does not expect to have any open contracts with customers as of December 31, 2017, the adoption of this standard is not expected to have a material impact on the Company's financial statements.

#### 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.

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, 2017 and December 31, 2016 (in thousands):

June 30, 2017

Adjusted Unrealized Unrealized Fair Cost Gains Loss Value Cash and Cash Restricted Marketable Cash Securities

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\$5,283 \$ Cash \_\$ \_ \$5,283 \$ 3,870 \$ 1,413 \$ — Level 1 (1): Money market funds 10,167 — 10,167 10,167 Level 2 (2): U.S. government agency securities 70,222 — (59 ) 70,163 — 70,163 \$85,672 \$ —\$ (59 ) \$85,613 \$ 14,037 \$ 1,413 \$ 70,163 Total

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	December	31,	2016						
	Adjusted Cost	Un: Gai		Unrealiz Losses	ed	Fair Value	Cash and Cash Equivalent	Restricted Cash	Marketable Securities
Cash	\$13,756	\$	_	\$ —		\$13,756	\$ 12,563	\$ 1,193	\$ —
Level 1 (1): Money market funds	10,043	_		_		10,043	10,043	_	_
Level 2 (2):									
Cash and cash equivalents	1,660	_				1,660	1,660	_	_
U.S. government agency securities	86,333	19		(17	)	86,335		_	86,335
Subtotal	87,993	19		(17	)	87,995	1,660	_	86,335
Total	\$111,792	\$	19	\$ (17	)	\$111,794	\$ 24,266	\$ 1,193	\$ 86,335

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

The Company classifies investments available to fund current operations as current assets on its balance sheets. As of June 30, 2017, 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. The Company recorded an unrealized loss of \$(0.1) million and an unrealized gain of \$0.3 million during the six months ended June 30, 2017 and 2016, respectively. 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 six months ended June 30, 2017 and 2016. 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, 2017 or the year ended December 31, 2016.

#### Warrants

At June 30, 2017, there is an outstanding warrant to purchase up to 20,161 shares of the Company's common stock with a fair value recorded as a liability as it contains a cash settlement feature upon certain strategic transactions. The following table sets forth a summary of changes in the fair value of this warrant liability, which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs (in thousands):

	War	rant Li	ability
Balance as of December 31, 2016	\$	75	
Amounts acquired or issued	—		
Changes in estimated fair value	(56		)

<sup>(2)</sup> 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.

Balance as of June 30, 2017 \$ 19

On each re-measurement date, the fair value of the warrant classified as a liability is estimated using the Black-Scholes option pricing model. For this liability, the Company develops its own assumptions that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the

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Company's common stock, stock price volatility, the contractual term of the warrant, risk-free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrant is considered a Level 3 measurement. The following assumptions were used at June 30, 2017 and December 31, 2016 to value the warrant liability:

	June 30		
	2017	31, 201	10
Estimated remaining term	4.9	5.3	
	years	years	
Risk-free interest rate	1.8 %	2.0	%
Volatility	77.6 %	77.2	%
Dividend yield	0 %	0	%
Fair value of underlying instrument*	\$2.30	\$ 5.88	

<sup>\*</sup> Trevena, Inc. closing stock price.

The warrant liability is recorded on its own line item on the Company's balance sheets and is marked-to-market at each reporting period with the change in fair value recorded on its own line in the statements of operations and comprehensive loss.

In addition to the outstanding warrant to purchase 20,161 shares of common stock discussed above, the Company has outstanding warrants to purchase an aggregate of 102,930 shares of the Company's common stock. These warrants qualify for equity classification and have been allocated upon the relative fair value of the base instrument and the warrants. See Note 4 for additional information.

#### 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 is required to make payments of interest only on borrowings under the loan agreement on a monthly basis through and including January 1, 2018, after which payments of principal in equal monthly installments and accrued interest will 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 2.0% of the total amount prepaid if the prepayment occurs between December 23, 2016 and December 23, 2017, and 1.0% of the total amount prepaid if the

prepayment occurs on or after December 24, 2017.

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, other than intellectual property. 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

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material adverse change in the collateral, the Company's business, operations or condition (financial or otherwise), certain levies, attachments and other restraints on the Company's business, insolvency, defaults under other agreements and misrepresentations.

In connection with entering into the original agreement, the Company issued to the lenders and the placement agent warrants to purchase an aggregate of 7,678 shares of the Company's common stock; warrants to purchase an aggregate of 5,728 shares remain outstanding as of June 30, 2017. These warrants are exercisable immediately and have an exercise price of \$5.861 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 the Company's common stock. These warrants have substantially the same terms as those described above, and 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 our common stock. 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.

As of June 30, 2017, borrowings of \$28.5 million attributable to Term Loans A, B, and C remain outstanding. Interest expense of \$0.5 million was recorded during each of the six months ended June 30, 2017and 2016. The Company incurred lender and third party costs of \$0.2 million and \$0.1 million, respectively, related to the issuance of Term Loan A. The Company incurred immaterial lender and third party costs related to the issuance of Term Loans B and C. The lender costs are classified as a debt discount and the third party costs are classified as debt issuance costs. 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 six months ended June 30, 2017and 2016 respectively.

The following table summarizes how the issuance of Term Loans A, B, and C are reflected on the balance sheet at June 30, 2017 and December 31, 2016 (in thousands):

	June 30,	December
	2017	31, 2016
Gross proceeds	\$28,500	\$18,500
Debt discount and debt issuance costs	(512)	(191)
Carrying value	27,988	18,309
Current portion of loans payable, net	7,093	5,039
Loans payable, net	\$20,895	\$13,270

## 5. Stockholders' Equity

## **Equity Offerings**

On December 14, 2015, the Company entered into an at the market, or ATM, sales agreement with Cowen and Company, LLC, or Cowen, to offer and sell, from time to time at its sole discretion, shares of its common stock, par value \$0.001 per share, having an aggregate offering price of up to \$75.0 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 of 1933,

as amended. 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. In 2016, the Company issued and sold 4,815,491 shares of common stock under this ATM facility at a weighted average price per share of \$6.865. The net offering proceeds to the Company were approximately \$32.1 million after deducting related expenses, including commissions. In the six months ended June 30, 2017, the Company issued and sold an additional 3,403,955 shares of common stock under the ATM facility at a weighted average price per share of \$4.13. The net offering proceeds to the Company were approximately \$13.7 million after deducting related expenses, including commissions. As of June 30, 2017, approximately \$27.9 million remained available under the ATM facility.

**Equity Incentive Plans** 

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As further described below, we have three share-based compensation plans that authorize the Company 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.

On December 15, 2016, the Company adopted the Trevena, Inc. Inducement Plan, or the Inducement Plan, which became effective on January 1, 2017. Under the Inducement Plan, the Company reserved 500,000 shares of the Company's common stock for issuance as nonstatutory stock options and restricted stock unit awards, of which 400,000 shares remain available for issuance as of June 30, 2017. The only persons eligible to receive grants of awards under the Inducement Plan are individuals who satisfy the standards for inducement grants under NASDAQ Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1, including individuals who were not previously an employee or director of the Company or are following a bona fide period of non-employment, in each case as an inducement material to such individual's agreement to enter into employment with the Company. In addition, the Company may grant stock awards under the 2013 Equity Incentive Plan to employees, including officers, non-employee directors and consultants of the Company.

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):

**Options Outstanding** 

	Three Months		Six Mo	nths
	Ended J	June 30,	Ended J	June 30,
	2017	2016	2017	2016
Research and development	\$735	\$623	\$1,441	\$1,129
General and administrative	1,158	887	2,246	1,584
Total stock-based compensation	\$1,893	\$1,510	\$3,687	\$2,713

Exercisable at June 30, 2017

	1		
			Weighted
		Weighted	Average
	Number of	Average	Remaining
	Shares	Exercise	Contractual
		Price	Term (in
			years)
Balance, December 31, 2016	6,370,578	\$ 6.10	7.6
Granted	2,826,844	4.72	
Exercised	(283,995)	1.25	
Forfeited/Cancelled	(393,275)	6.80	
Balance, June 30, 2017	8,520,152	\$ 5.78	8.02
Vested or expected to vest at June 30, 2017	8,520,152	\$ 5.78	8.02

The intrinsic value of the options exercisable as of June 30, 2017 was \$0.7 million, based on the Company's closing stock price of \$2.30 per share and a weighted average exercise price of \$5.19 per share. At June 30, 2017, there was \$17.7 million of total unrecognized compensation expense related to unvested options that will be recognized over the weighted average remaining period of 2.90 years.

6.58

3,514,623 \$ 5.19

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, 2017 and 2016 was estimated at \$3.20 and \$5.34 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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Shares Available for Future Grant

At June 30, 2017, the Company has the following shares available to be granted under the 2013 Plan and the Inducement Plan:

	2013 Plan	Inducement Plan
Available at December 31, 2016	1,101,331	
Authorized	2,230,736	500,000
Granted	(2,726,844)	(100,000 )
Forfeited/Cancelled	393,275	
Available at June 30, 2017	998,498	400,000

Shares Reserved for Future Issuance

At June 30, 2017, the Company has reserved the following shares of common stock for issuance:

Stock options outstanding	8,520,152
Shares available for future grant under 2013 Plan	998,498
Shares available for future grant under Inducement Plan	400,000
Employee stock purchase plan	225,806
Warrants outstanding	123,091
Total shares of common stock reserved for future issuance	10,267,547

## 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. Revenue

For arrangements with multiple elements, the Company recognizes revenue in accordance with the FASB's Accounting Standards Update No. 2009-13, Multiple-Deliverable Revenue Arrangements, which provides guidance for separating and allocating consideration in a multiple element arrangement. Deliverables under the arrangement are separate units of accounting if the delivered item has value to the customer on a standalone basis and if the arrangement includes a general right of return relative to the delivery or performance of the undelivered item is considered probable and substantially within the Company's control. The consideration that is fixed or determinable at

the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting, the Company evaluates whether the components have standalone value to the collaborator based on consideration of the relevant facts and circumstances for each arrangements. Whenever the Company determines that an element is delivered over a period of time, revenue is recognized using either a proportional

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performance model, if a pattern of performance can be determined, or a straight-line model over the period of performance, which is typically the research and development term.

The Company entered into a letter agreement with Allergan plc in March 2015 under which the Company received a nonrefundable upfront fee of \$10.0 million. The terms of this agreement contained multiple deliverables which include (i)

research and development activities and (ii) testing and analysis related to the Phase 2b trial of TRV027. Collaboration revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or the services have been rendered, and the Company has fulfilled its performance obligations under the contract. The collaboration revenue was recorded on a straight-line basis and was fully recognized as of June 30, 2016. For the three and six months ended June 30, 2016, the Company recognized collaboration revenue of \$1.9 million and \$3.8 million, respectively.

#### 8. 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 Mon	nths Ended	Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Basic and diluted net loss per common share calculation:				
Net loss	\$(20,432)	\$(19,216)	\$(41,146)	\$(36,995)
Net loss attributable to common stockholders	\$(20,432)	\$(19,216)	\$(41,146)	\$(36,995)
Weighted average common shares outstanding	58,381,86	852,174,569	57,642,37	951,762,467
Net loss per share of common stock - basic and diluted	\$(0.35)	\$(0.37)	\$(0.71)	\$(0.71)

The following outstanding securities at June 30, 2017 and 2016 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

June 30, 2017 2016 Options outstanding 8,520,152 6,480,580 Warrants 123,091 60,850 Total 8,643,243 6,541,430

### 9. Other Comprehensive Income (Loss)

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

```
Balance, December 31, 2016 $2

Net unrealized loss on marketable securities (59)

Balance, June 30, 2017 $(57)
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There were no reclassifications out of accumulated other comprehensive income (loss) during the six months ended June 30, 2017 and 2016. There was no tax effect during the three and six months ended June 30, 2017 and 2016.

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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, 2016, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 8, 2017. 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:

OLINVO<sup>TM</sup> (oliceridine injection): We are developing OLINVO, a μ-receptor G protein pathway selective modulator, or µ-GPS, for the management of moderate-to-severe acute pain where intravenous, or IV, administration is preferred. On February 21, 2017, we announced positive top-line results from our Phase 3 APOLLO-1 and APOLLO-2 pivotal efficacy studies of OLINVO 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. On July 20, 2017, we announced that we have completed enrollment in the Phase 3 open-label ATHENA safety study to support the planned new drug application, or NDA, for OLINVO. In the study, 772 patients were administered OLINVO to manage pain associated with a wide range of procedures and diagnoses. We have retained all worldwide development and commercialization rights to OLINVO. If OLINVO 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 OLINVO with a commercial partner. In early April 2017, we held a successful Type B meeting with the United States Food and Drug Administration, or FDA, regarding the Chemistry, Manufacturing and Controls data package of our new drug application, or NDA, submission for OLINVO. In the second quarter of 2017, we held another successful pre-NDA meeting with FDA regarding the clinical and non-clinical data package of the planned NDA. The Company currently expects to submit the NDA in September or October of 2017.

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 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  $\mu$ -opioid related adverse effects like those seen with morphine or oxycodone. In the second quarter of 2017, we began a Phase I study of TRV250 in the United Kingdom in healthy volunteers; results from this study are expected in the second half of 2017.

We have also 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. We intend to continue to focus our efforts for TRV734 on securing a development and commercialization partner for this asset. 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, 2017, we had an accumulated deficit of \$326.8 million. Our net loss was \$41.1 million and \$37.0 million for the six months ended June 30, 2017 and 2016, 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 OLINVO, 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 we have drawn \$28.5 million as of June 30, 2017.

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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. If we obtain regulatory approval for OLINVO, 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 additional 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 research and 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 \$35.0 million in a three-tranche series of term loans (Term Loans A, B, and C). Upon initially entering into the agreement, we borrowed \$2.0 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 \$10.0 million of Term Loan C. In March 2017, we 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. We are required to make payments of interest only on borrowings under the loan agreement on a monthly basis through and including January 1, 2018, after which payments of principal in equal monthly installments and accrued interest will be due 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 2.0% of the total amount prepaid if the prepayment occurs between December 23, 2016 and December 23, 2017, and 1.0% of the total amount prepaid if the prepayment occurs on or after December 24, 2017.

Our obligations are secured by a first priority security interest in substantially all of our assets, other than intellectual property. In addition, we have agreed not to pledge or otherwise encumber our intellectual property, with specified exceptions.

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, 2017. 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. 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. 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, 2016 included in our annual report on Form 10-K. However, we believe that the following

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accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this discussion.

## Research and Development

Research and development costs are charged to expense as incurred. These costs include, but are not limited to, employee related expenses, including salaries, benefits and travel and stock based compensation of our research and development personnel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; other laboratory supplies; allocated facilities, depreciation and other expenses, which include rent and utilities; insurance; and costs associated with preclinical activities and regulatory operations.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

As part of the process of preparing our financial statements, we are required to estimate our expenses resulting from our obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. Our objective is to reflect the appropriate trial expenses in our financial statements by matching those expenses with the period in which services are performed and efforts are expended. We may account for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial. We determine accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from estimates. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us at that time. Our clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the three and six months ended June 30, 2017 and 2016, there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

## **Stock-Based Compensation**

We have applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation - Stock Compensation 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.

Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock-based awards as of their measurement date. We recognize stock-based compensation expense over the requisite service period, which is the vesting period of the award. Calculating the fair value of stock-based awards requires that we make highly subjective assumptions. We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our

common stock, the fair value of our common stock on the measurement date, the expected term of our stock options, the risk free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Because of our limited operating history as a publicly traded entity, we utilize data from a representative group of publicly traded companies to estimate expected stock price volatility. We selected representative companies from the biopharmaceutical industry with characteristics similar to us. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, as we do not have sufficient historical stock option activity data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. 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. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

Under ASC 718, we are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. In March 2016, the FASB issued ASU 2016-09,

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Compensation - Stock Compensation (Topic 718) which provides for improvements to employee share-based payment accounting. In connection with the early adoption of ASU 2016-09 in the quarter ended December 31, 2016, the Company elected an accounting policy to record forfeitures as they occur.

## **Recent Accounting Pronouncements**

See Note 2, Summary of Significant Accounting Policies, in the notes to our unaudited financial statements for the three and six months ended June 30, 2017, 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 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, 2017 and 2016 (in thousands)

	Three Months Ended			Six Months Ended			
	June 30,			June 30,			
	2017	2016	Change	2017	2016	Change	
Revenue:							
Collaboration revenue	<b>\$</b> —	\$1,875	\$(1,875)	<b>\$</b> —	\$3,750	\$(3,750)	
Total revenue	_	1,875	(1,875)	_	3,750	(3,750)	
Operating expenses:							
General and administrative	4,385	3,697	688	9,264	7,615	1,649	
Research and development	15,499	17,203	(1,704)	31,595	32,956	(1,361)	
Total operating expenses	19,884	20,900	(1,016)	40,859	40,571	288	
Loss from operations	(19,884)	(19,025)	(859)	(40,859)	(36,821)	(4,038)	
Other income (expense):							
Change in fair value of warrant liability	21	28	(7)	56	70	(14)	
Net (loss) gain on asset disposals	1	_	1	1	_	1	
Miscellaneous income	_	_	_	628	221	407	
Interest income	163	214	(51)	337	407	(70)	
Interest expense	(733)	(433)	(300)	(1,309)	(872)	(437)	
Total other expense	(548)	(191)	(357)	(287)	(174)	(113)	
Net loss attributable to common stockholders	\$(20,432)	\$(19,216)	\$(1,216)	\$(41,146)	\$(36,995)	\$(4,151)	

### Revenue

To date, we have derived revenue principally from research grants and collaboration arrangements. In March 2015, we signed a letter agreement with Allergan plc pursuant to which it paid us \$10.0 million to fund the expansion of our Phase 2b trial of TRV027 from 500 patients to 620 patients. The collaboration revenue was recorded on a straight-line basis over the remaining period of the trial and was fully recognized as of June 30, 2016.

## General and administrative expense

General and administrative expenses consist principally of salaries and related costs for administrative personnel, including stock based compensation and travel expenses. Other general and administrative expenses include professional fees for legal, consulting and accounting services.

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General and administrative expenses increased by \$0.7 million, or 19%, and \$1.6 million, or 22%, respectively, for the three and six months ended June 30, 2017, as compared to the same period in 2016, primarily as a result of increased headcount and associated salary and stock-based compensation expense, and increased market research expenditures related to OLINVO.

#### 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.

Research and development expenses decreased by \$1.7 million, or 10%, for the three months ended June 30, 2017, as compared to the same period in 2016 and decreased by \$1.4 million or 4% for the six months ended June 30, 2017, as compared to the same period in 2016. The following table summarizes our research and development expenses (in thousands):

	Three M	onths	Six Months		
	Ended		Ended		
	June 30,		June 30,		
	2017	2016	2017	2016	
Personnel-related costs	\$3,478	\$3,112	\$7,174	\$6,158	
OLINVO	9,670	10,085	20,426	17,130	
TRV027	20	1,895	113	5,348	
TRV250	898	954	1,341	2,258	
Other research and development	1,433	1,157	2,541	2,062	
	\$15,499	\$17,203	\$31,595	\$32,956	

The decrease in research and development expenses during the three and six months ended June 30, 2017 was primarily due to a decrease in expenditures related to TRV027 due to the completion of the Phase 2b clinical trial in AHF during the second quarter of 2016, partially offset by increased expenditures on OLINVO in the first half of 2017 attributable to the Phase 3 open-label ATHENA safety study.

## 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, 2017, we had an accumulated deficit of \$326.8 million, working capital of \$75.4 million, cash and cash equivalents of \$14.0 million, restricted cash of \$1.4 million, and marketable securities of \$70.2 million.

#### Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2017 and 2016 (in thousands):

Six Months Ended

June 30,

2017 2016

Net cash (used in) provided by:

Operating activities \$(47,748) \$(39,236)
Investing activities 13,778 17,414
Financing activities 23,960 11,851
Net decrease in cash, cash equivalents and restricted cash \$(10,010) \$(9,971)

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Net cash used in operating activities

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 OLINVO. 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.

Net cash used in operating activities was \$39.2 million for the six months ended June 30, 2016, consisting primarily of a net loss of \$37.0 million partially offset by noncash adjustments of \$3.8 million and changes in operating assets and liabilities of \$6.1 million. Changes in operating assets and liabilities were primarily driven by a decrease of deferred revenue of \$3.8 million associated with the payment received from Allergan in March 2015, partially offset by a decrease in prepaid expenses and other assets of \$1.2 million and a decrease in accounts payable and accrued expenses of \$1.1 million. These 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.

Net cash used in investing activities

Net cash used in investing activities was \$13.8 million for the six months ended June 30, 2017 and \$17.4 million for the six months ended June 30, 2016. Investing activities in both years consisted primarily of purchases and maturities of marketable securities, as well as expenditures related to leasehold improvements and the purchase of capital equipment.

Net cash provided by financing activities

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 at-the-market, or ATM, sales facility with Cowen and Company, LLC, or Cowen.

Net cash provided by financing activities was \$11.9 million for the six months ended June 30, 2016, which was due to net proceeds of \$11.8 million from the sale of common stock through Cowen, pursuant to our ATM sales facility, and proceeds from exercises of common stock options.

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 continue open label investigations of OLINVO in key procedures, prepare the OLINVO NDA submission, prepare for future regulatory activities, and continue clinical development of TRV250. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, 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 any future products.

We believe that our cash and cash equivalents and marketable securities as of June 30, 2017, together with interest thereon, will be sufficient to fund our operating expenses and capital expenditure requirements into the third quarter of 2018. 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 December 2015, we filed a \$250 million shelf registration statement that

includes a \$75 million ATM sales facility with Cowen acting as our sales agent. Approximately \$27.9 million remained available under the ATM sales facility as of June 30, 2017. 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:

the progress, timing and results of the NDA submission for OLINVO and related regulatory activities;

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our ability to enter into collaborative agreements for the development and/or commercialization of our product candidates, including for OLINVO;

the number and development requirements of any other product candidates that we may pursue;

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

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;

any product liability or other lawsuits related to our products;

the expenses needed to attract and retain skilled personnel;

the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and

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 and our most recent Annual Report on Form 10-K as filed with the SEC and which is incorporated herein by reference, 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, 2017 (in thousands):

	I dy men				
		Less than	1 - 3	2 5	More
	Total	than			than
		1 Year	years	years	5 years
Operating lease obligations(1)	\$12,889	\$945	\$2,416	\$2,378	\$7,150
Loans payable	\$28,500	\$7,389	\$21,111	<b>\$</b> —	<b>\$</b> —
Total	\$41,389	\$8,334	\$23,527	\$2,378	\$7,150

Payments Due By Period

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

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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. We did not make any significant changes to our critical accounting policies during the six months ended June 30, 2017.

**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 \$14.0 million and marketable securities of \$70.2 million at June 30, 2017, 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 Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017, 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

None.

#### ITEM 1A. RISK FACTORS

There have been no material changes to our risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016, with the exception of the following risk factors:

If serious adverse or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

If our product candidates are associated with adverse side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the compound or significantly limited its commercial opportunity. In March 2017, a patient in our Phase 3 open label ATHENA study experienced an apparent off-target, unexpected serious adverse event after hospital discharge that has been assessed as possibly related to drug. This event was reported to FDA in early April 2017 and, as of the date of this report, we have not been contacted by FDA about this event. To date, approximately 770 patients have received OLINVO in the ATHENA study, including many with significant co-morbidities that may contribute to the occurrence of adverse effects. In the event that our clinical trials reveal a high and unacceptable severity and prevalence of side effects, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

Additionally if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

• regulatory authorities may require additional warnings on the label or even withdraw approvals of such product;

we may be required to create a medication guide outlining the risks of such side effects for distribution to patients, if one is not required in connection with regulatory approval;

we could be sued and held liable for harm caused to patients; and our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

OLINVO is predominantly metabolized by two liver enzymes, CYP2D6 and CYP3A4, that are common metabolic pathways for drugs. Because of competitive use of these pathways, we may need to conduct additional drug interaction studies and OLINVO may be limited in its co-administration with other drugs using these pathways as their safety and effectiveness, as well as OLINVO's, may be adversely affected. This could limit our commercial opportunity due to the common co-administration of drugs in patients with moderate-to-severe acute pain requiring IV therapy. In addition, since CYP2D6 enzyme activity varies in the population, different dosing may be required in the product label for individuals that have low levels of CYP2D6 activity, which could limit the commercial opportunity of the drug, if approved. We continue to discuss this question with the FDA and cannot assure you that the FDA will

not require us to utilize different dosing for this population and/or prospectively characterize individuals' CYP2D6 activity prior to administering OLINVO.

OLINVO and TRV734 are both biased ligands targeted at the  $\mu$ -opioid receptor. Common adverse reactions for agonists of the  $\mu$ -opioid receptor include respiratory depression, constipation, nausea, vomiting, and addiction. In rare cases,  $\mu$ -opioid receptor agonists can cause respiratory arrest requiring immediate medical intervention. Since OLINVO and TRV734 also modulate the  $\mu$ -opioid receptor, these adverse reactions and risks likely will apply to the use of OLINVO and TRV734. One healthy subject in the 0.25 mg dosing cohort of our Phase 1 clinical trial of OLINVO experienced a severe episode of vasovagal syncope during which he fainted and his pulse stopped. These were considered severe adverse events. It is possible that serious adverse vasovagal events could occur in other patients dosed with OLINVO. Agonists at the -opioid receptor have

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been associated with a risk of seizures. TRV250, our -opioid receptor product candidate, targets the same receptor as other programs that have been associated with seizures and, accordingly, it is possible that it will be associated with similar side effects. In such case, we likely would discontinue further development of TRV250 for the treatment of migraines.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Quarterly Report on Form 10-Q.

# Exhibit Number Description

- First amendment dated June 12, 2017 to Agreement of Lease between Chesterbrook Partners, LP and Trevena, Inc. for 955 Chesterbrook Blvd., Suite 200, Chesterbrook, PA as of December 9, 2016.
- Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
- Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
- 32.1\* Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2\* Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

The following financial information from this Quarterly Report on Form 10-Q for the six months ended June 30, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets as of June 30, 2017 and December 31, 2016, (ii) Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2017 and 2016, (iii) Statement of Stockholders' Equity for the period from January 1, 2017 to June 30, 2017, (iv) Statements of Cash Flows for the six months ended June 30, 2017 and 2016 and (v) Notes to Unaudited Financial Statements, tagged as blocks of text.

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\* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Exchange Act and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 3, 2017

TREVENA, INC.

By:/s/ ROBERTO CUCA

Roberto Cuca

Senior Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

**EXHIBIT INDEX** 

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