

TREVENA INC
Form 10-Q
November 10, 2015
Table of Contents

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, 2015

Or

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

For the transition period from _____ to _____

Commission File Number 001-36193

Trevena, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

26-1469215
(I.R.S. Employer
Identification No.)

1018 West 8th Avenue, Suite A
King of Prussia, PA
(Address of Principal Executive Offices)

19406
(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: **None**

(Title of Class)

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. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act.:

Large accelerated filer

Accelerated filer

Edgar Filing: TREVENA INC - Form 10-Q

Non-accelerated filer
(Do not check if a smaller reporting company)

Smaller reporting company

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

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 5, 2015: 50,767,027

Table of Contents

TABLE OF CONTENTS

	Page
<u>Cautionary Note Regarding Forward-Looking Statements</u>	1
	PART I- FINANCIAL INFORMATION
<u>Item 1.</u>	
	<u>Financial Statements (unaudited)</u>
	<u>Balance Sheets</u> 2
	<u>Statements of Operations and Comprehensive Loss</u> 3
	<u>Statement of Stockholders' Equity</u> 4
	<u>Statements of Cash Flows</u> 5
	<u>Notes to Unaudited Financial Statements</u> 6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 15
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 23
<u>Item 4.</u>	<u>Controls and Procedures</u> 23
	PART II- OTHER INFORMATION
<u>Item 1.</u>	<u>Legal Proceedings</u> 24
<u>Item 1A.</u>	<u>Risk Factors</u> 24
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 24
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u> 24
<u>Item 4.</u>	<u>Mine Safety Disclosures</u> 24
<u>Item 5.</u>	<u>Other Information</u> 24
<u>Item 6.</u>	<u>Exhibits</u> 25
 <u>SIGNATURES</u>	 26

Table of Contents

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, plan, objective, estimate, predict, project, potential, continue and ongoing, or the negative of these 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;
- the exercise by Allergan plc (formerly Actavis plc and Forest Laboratories Holdings Limited) of its option to license TRV027 and, if exercised, our ability to achieve milestones under the license;
- our planned clinical trials and preclinical studies for our product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the extent of clinical trials potentially required by the FDA for our product candidates;
- the clinical utility and market acceptance of our product candidates;
- 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 the 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.

Table of Contents**PART I****ITEM 1. FINANCIAL STATEMENTS****TREVENA, INC.****Balance Sheets**

	September 30, 2015 (unaudited)	December 31, 2014 As Adjusted
Assets		
Current assets:		
Cash and cash equivalents	\$ 39,034,709	\$ 36,205,559
Marketable securities	129,937,375	70,698,640
Prepaid expenses and other current assets	986,875	669,155
Total current assets	169,958,959	107,573,354
Property and equipment, net	601,476	553,294
Restricted cash	112,410	112,410
Total assets	\$ 170,672,845	\$ 108,239,058
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,360,667	\$ 4,342,480
Accrued expenses and other current liabilities	2,670,607	2,578,269
Deferred revenue	5,625,000	
Deferred rent	41,818	38,359
Total current liabilities	10,698,092	6,959,108
Loan payable, net	1,777,667	1,692,884
Capital lease, net of current portion	8,642	10,677
Deferred rent, net of current portion	250,841	281,885
Warrant liability	153,953	82,851
Other long term liabilities	40,430	8,025
Total liabilities	12,929,625	9,035,430
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized 50,736,251 and 39,241,173 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	50,736	39,241
Additional paid-in capital	324,683,788	231,152,894
Accumulated deficit	(167,033,704)	(131,969,725)
Accumulated other comprehensive income (loss)	42,400	(18,782)
Total stockholders' equity	157,743,220	99,203,628
Total liabilities and stockholders' equity	\$ 170,672,845	\$ 108,239,058

See accompanying notes to financial statements.

Table of Contents**TREVENA, INC.****Statements of Operations and Comprehensive Loss (unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue:				
Collaboration revenue	\$ 1,875,000	\$	\$ 4,375,000	\$
Total revenue	1,875,000		4,375,000	
Operating expenses:				
General and administrative	2,780,115	2,536,807	8,977,000	7,033,492
Research and development	9,650,138	13,006,568	30,524,601	29,671,114
Total operating expenses	12,430,253	15,543,375	39,501,601	36,704,606
Loss from operations	(10,555,253)	(15,543,375)	(35,126,601)	(36,704,606)
Other income (expense):				
Change in fair value of warrant liability	(68,037)	11,181	(71,102)	109,522
Gain on asset disposal			2,656	
Miscellaneous income	731		174,266	184,015
Interest income	79,407	1,809	172,095	11,589
Interest expense	(72,331)	(4,487)	(215,293)	(4,487)
Total other income (expense)	(60,230)	8,503	62,622	300,639
Net loss and comprehensive loss	(10,615,483)	(15,534,872)	(35,063,979)	(36,403,967)
Accretion of redeemable convertible preferred stock				(28,521)
Net loss attributable to common stockholders	\$ (10,615,483)	\$ (15,534,872)	\$ (35,063,979)	\$ (36,432,488)
Per share information:				
Net loss per share of common stock, basic and diluted	\$ (0.24)	\$ (0.59)	\$ (0.85)	\$ (1.58)
Weighted average shares outstanding, basic and diluted	44,214,428	26,366,300	41,443,362	23,036,366

See accompanying notes to financial statements.

Table of Contents**TREVENA, INC.****Statement of Stockholders Equity (unaudited)**

For the period from January 1, 2015 to September 30, 2015

	Common Stock		Stockholders Equity		Accumulated Other Comprehensive Income/(Loss)	Total Stockholders Equity
	Number of Shares	\$0.001 Par Value	Additional Paid-in Capital	Accumulated Deficit		
Balance, January 1, 2015	39,241,173	\$ 39,241	\$ 231,152,894	\$ (131,969,725)	\$ (18,782)	\$ 99,203,628
Stock-based compensation expense			2,348,526			2,348,526
Exercise of stock options	317,681	318	682,735			683,053
Net exercise of common stock warrant	2,397	2	(2)			
Issuance of common stock, net of issuance costs	11,175,000	11,175	90,499,635			90,510,810
Unrealized gains on marketable securities					61,182	61,182
Net loss				(35,063,979)		(35,063,979)
Balance, September 30, 2015	50,736,251	\$ 50,736	\$ 324,683,788	\$ (167,033,704)	\$ 42,400	\$ 157,743,220

See accompanying notes to financial statements.

Table of Contents**TREVENA, INC.****Statements of Cash Flows (unaudited)**

	Nine Months Ended September 30,	
	2015	2014
Operating activities:		
Net loss	\$ (35,063,979)	\$ (36,403,967)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	155,257	184,868
Stock-based compensation	2,348,526	1,889,932
Noncash interest expense on loans	117,188	
Amortization of bond premium in marketable securities	758,337	
Revaluation of warrant liability	71,102	(109,522)
Changes in operating assets and liabilities:		
Prepaid expenses, offering costs and other assets	(317,720)	2,946,831
Accounts payable and accrued expenses	(1,917,189)	4,762,085
Deferred revenue	5,625,000	
Net cash used in operating activities	(28,223,478)	(26,729,773)
Investing activities:		
Purchase of property and equipment	(203,440)	(421,517)
Maturities of marketable securities	48,350,000	
Purchases of marketable securities	(108,285,889)	
Net cash used in investing activities	(60,139,329)	(421,517)
Financing activities:		
Proceeds from exercise of common stock options	683,053	101,058
Proceeds from issuance of common stock, net	90,510,810	59,534,984
Net proceeds from debt issuance		1,775,012
Capital lease payments	(1,906)	(405)
Net cash provided by financing activities	91,191,957	61,410,649
Net increase in cash and cash equivalents	2,829,150	34,259,359
Cash and cash equivalents beginning of period	36,205,559	37,965,198
Cash and cash equivalents end of period	\$ 39,034,709	\$ 72,224,557

See accompanying notes to financial statements.

Table of Contents

TREVENA, INC.

Notes to Unaudited Financial Statements

September 30, 2015

1. Organization and Description of the Business

Trevena, Inc. (the Company) is a Delaware corporation that commenced operations in December 2007. The Company is a clinical stage biopharmaceutical company that discovers, develops and intends to commercialize therapeutics that use a novel approach to target G protein coupled receptors. The Company operates in one segment and has its principal office in King of Prussia, Pennsylvania.

Liquidity

At September 30, 2015, the Company had an accumulated deficit of \$167.0 million and its net loss was \$35.1 million and \$36.4 million for the nine months ended September 30, 2015 and 2014, respectively. The Company expects its cash and cash equivalents of \$39.0 million and marketable securities of \$129.9 million as of September 30, 2015, together with interest thereon, to be sufficient to fund its operating expenses and capital expenditure requirements into 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 (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 (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB). The Company considers the U.S. dollar to be its functional currency.

Unaudited Interim Financial Information

Edgar Filing: TREVENA INC - Form 10-Q

The accompanying financial statements are unaudited. The interim unaudited financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2015 and the results of its operations, its comprehensive loss and its cash flows for the three and nine months ended September 30, 2015 and 2014. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2015 and 2014 are not necessarily indicative of the results to be expected for any future interim period or for the year ending December 31, 2015 or any future year.

Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 of the Notes to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies.

Use of Estimates

Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. In preparing these financial statements, management used significant estimates in the following areas, among others: stock-based compensation expense, the determination of the fair value of stock-based awards, the fair value of liability-classified stock warrants, the accounting for research and development costs, accrued expenses and the recoverability of the Company's net deferred tax assets and related valuation allowance.

Table of Contents

Recent Accounting Pronouncements

On April 7, 2015, the FASB issued Accounting Standards Update 2015-03, Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03). ASU 2015-03 requires debt issuance costs to be presented in the balance sheets as a direct deduction from the associated debt liability. Although the standard is retrospectively effective for annual reporting periods beginning after December 15, 2015, early adoption is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued. The Company elected early adoption during the first quarter of 2015 which resulted in a balance sheet adjustment as of December 31, 2014 of \$98,401 to other assets and loans payable, net. The Company's adoption of this standard did not have a significant impact on its results of operations or cash flows. See Note 4.

In May 2014, the FASB issued Accounting Standards Update 2014-09 Revenue from Contracts with Customers (ASU 2014-09). 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. In July 2015, the FASB decided to defer the effective date of the standard from January 1, 2017, to January 1, 2018, with an option that permits companies to adopt the standard as early as the original effective date. Early application prior to the original effective date is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. 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

Cash, Cash Equivalents and Marketable Securities

All highly liquid investments that have maturities of three months or less when acquired are considered by the Company to be cash equivalents and are valued at cost, which approximates their fair market value. The Company classifies its marketable securities as available-for-sale, carries them at fair market value and classifies them as current assets on its balance sheets. Unrealized gains and losses on marketable securities are recorded as a separate component of accumulated other comprehensive income/(loss) included in stockholders' equity. There were no charges taken for other-than-temporary declines in fair value of investments during the three and nine months ended September 30, 2015 and 2014.

The following tables shows the Company's cash and available-for-sales securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category recorded as cash and cash equivalents or marketable securities as of September 30, 2015 and December 31, 2014:

Adjusted Cost	Unrealized Gains	September 30, 2015		Cash and Cash Equivalents	Marketable Securities
		Unrealized Losses	Fair Value		

Edgar Filing: TREVENA INC - Form 10-Q

Cash	\$	10,842,926	\$		\$	10,842,926	\$	10,842,926	\$			
Level 1 (1):												
Money market funds		4,191,613				4,191,613		4,191,613				
U.S. Treasury securities		24,090,948		12,652		24,103,600				24,103,600		
Subtotal		28,282,561		12,652		28,295,213		4,191,613		24,103,600		
Level 2 (2):												
Repurchase agreements		23,000,000				23,000,000		23,000,000				
U.S. agency securities		106,804,197		33,355		(3,607)		106,833,945		1,000,170	105,833,775	
Subtotal		129,804,197		33,355		(3,607)		129,833,945		24,000,170	105,833,775	
Total	\$	168,929,684	\$	46,007	\$	(3,607)	\$	168,972,084	\$	39,034,709	\$	129,937,375

											December 31, 2014		
		Adjusted Cost		Unrealized Gains		Unrealized Losses		Fair Value		Cash and Cash Equivalents		Marketable Securities	
Cash	\$	7,141,548	\$		\$		\$	7,141,548	\$	7,141,548	\$		
Level 1 (1):													
Money market funds		29,064,011						29,064,011		29,064,011			
U.S. Treasury securities		70,717,422		258		(19,040)		70,698,640				70,698,640	
Subtotal		99,781,433		258		(19,040)		99,762,651		29,064,011		70,698,640	
Total	\$	106,922,981	\$	258	\$	(19,040)	\$	106,904,199	\$	36,205,559	\$	70,698,640	

Table of Contents

(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 on the assets or liabilities.

As of September 30, 2015, the Company held \$37.5 million of available-for-sale investment securities with contractual maturity dates of more than one year and less than two years. The Company did not hold any investment securities exceeding a two-year maturity.

Warrant Liability

At September 30, 2015, 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 of \$153,953 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:

	Warrant Liability
Balance as of December 31, 2014	\$ 82,851
Changes in estimated fair value	71,102
Balance as of September 30, 2015	\$ 153,953

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 Company's common stock, stock price volatility, the contractual term of the warrants, risk-free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement. The following assumptions were used at September 30, 2015 and December 31, 2014 to determine the warrant liability:

	September 30, 2015 Common stock warrant liability	December 31, 2014 Common stock warrant liability
Estimated remaining term	6.59 years	7.34 years
Risk-free interest rate	1.67%	1.99%
Volatility	70%	72%
Dividend yield	0%	0%
Fair value of underlying instrument*	\$ 10.35	\$ 5.98

*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.

4. Long Term Debt

On September 19, 2014, the Company entered into a loan and security agreement with Oxford Finance LLC, as collateral agent and lender, and Square 1 Bank, as lender, pursuant to which the lenders have agreed to lend the Company up to \$35.0 million in a series of term loans. Upon entering into the agreement, the Company borrowed \$2.0 million from the lenders (Term Loan A). On April 13, 2015, the Company and the lenders amended the agreement to change the draw period for Term Loan B. As amended, the Company may now, at its sole discretion, borrow from the lenders:

- \$16.5 million, at any time beginning on October 1, 2015 and ending on December 31, 2015 (Term Loan B) since the Company has satisfied specified conditions precedent related to the results of the Company's ongoing Phase 2 studies of oliceridine (TRV130); and

Table of Contents

- an additional \$16.5 million, at any time on or before March 31, 2016 (Term Loan C and together with Term Loan A and Term Loan B, the Term Loans), subject to the Company's satisfaction of specified conditions precedent related to the results of the Company's ongoing Phase 2 studies of TRV027.

The proceeds from Term Loan A and future proceeds, if any, from Term Loan B and/or Term Loan C may be used to satisfy the Company's future working capital needs, potentially including the development of its clinical and preclinical product candidates.

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 term loans accrue interest at a fixed rate of 6.50% per annum. The Company is required to make payments of interest only on Term Loan A on a monthly basis through and including April 1, 2016 after which consecutive equal monthly payments of principal, plus accrued interest, will be due until December 1, 2018. Both of these dates may be modified with respect to the term loans, as applicable, as follows:

- If the Company meets the conditions to draw Term Loan C on or before March 31, 2016, then the date until which the Company is required to make payments of interest only will be extended from April 1, 2016 to October 1, 2016.
- If the Company meets the condition to draw Term Loan C on or before March 31, 2016, and the Company has received net cash proceeds of at least \$50.0 million from its existing strategic partnership and collaborative license option agreement with Allergan or another strategic partnership in form and substance satisfactory to the lenders, then the date until which consecutive equal monthly payments of principal, plus accrued interest, will be due will be extended from December 1, 2018 to September 1, 2019.

The Company has paid the lenders a facility fee of \$175,000 in connection with the execution of the loan and security agreement. Upon the last payment date of the amounts borrowed under the agreement, the Company will be required to pay the lenders a final payment fee equal to 6.1% of the term loans borrowed increased from the initial 5.25% as the Company has satisfied specified conditions precedent related to the results of the Company's completed Phase 2 bunionectomy study of oliceridine (TRV130) and subject to further adjustment as follows:

- If the Company meets the condition to draw Term Loan C on or before March 31, 2016, then the Company will be required to pay the lenders a final payment fee equal to 6.6% of the term loans borrowed; and

- If the Company meets the condition to draw Term Loan C on or before March 31, 2016, and the Company has received net cash proceeds of at least \$50.0 million from its existing strategic partnership and collaborative license option agreement with Allergan or another strategic partnership in form and substance satisfactory to the lenders, then the Company will be required to pay the lenders a final payment fee equal to 7.0%.

In addition, if the Company repays the term loans before the applicable maturity date, it will pay the lenders a prepayment fee of 3.00% of the total amount prepaid if the prepayment occurs prior to the first anniversary of the funding of the applicable term loan, 2.00% percent of the total amount prepaid if the prepayment occurs between the first and second anniversary of the funding of the applicable term loan, and 1.00% percent of the total amount prepaid if the prepayment occurs on or after the second anniversary of the funding of the applicable term loan.

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 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.

Three Point Capital, LLC served as a placement agent in connection with the term loans. The Company paid Three Point \$65,000 upon execution of the loan and security agreement and will be obligated to pay up to an additional \$175,000 if the Company draws on Term Loan B and Term Loan C.

Table of Contents

In connection with entering into the loan and security agreement, the Company issued to each of Oxford, Square 1 and Three Point warrants to purchase an aggregate of 7,678 shares of the Company's common stock. 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. The warrants are exercisable, in whole or in part, immediately, and have a per share exercise price of \$5.8610, which is the average closing price of the Company's common stock on the NASDAQ Global Market for the ten trading days prior to the effective date of the agreement. 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. If the Company borrows Term Loan B and/or Term Loan C, upon the funding of such Term Loan, the Company will issue additional warrants to purchase shares of the Company's common stock, each with a per share exercise price of \$5.8610 and on substantially the same terms as those contained in the warrants. The number of warrants issued or issuable by the Company is as follows:

Entity	Shares Underlying Warrants Issued on the Effective Date	Maximum Number of Shares Underlying Warrants Issuable Assuming Full Draw of Term Loan B	Maximum Number of Shares Underlying Warrants Issuable Assuming Full Draw of Term Loan C
Oxford	4,875	40,217	40,217
Square 1	1,950	16,087	16,087
Three Point	853	7,038	7,038

As of September 30, 2015, only Term Loan A has been issued, all of which remains outstanding as of such date. Interest expense of \$32,500 and \$97,500 was recorded during the three and nine months ended September 30, 2015, respectively. The Company incurred lender and third party costs of \$225,988 and \$106,545, respectively, related to the issuance of Term Loan A. The lender costs are classified as a debt discount and the third party costs are classified as debt issuance costs. Per ASU 2015-03, 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 Term Loan A using the effective interest method. A total of \$39,639 and \$117,188 of debt discount and debt issuance costs was amortized to interest expense during the three and nine months ended September 30, 2015, respectively.

The following table summarizes how the issuance of Term Loan A is reflected on the balance sheet at September 30, 2015:

	September 30, 2015
Gross proceeds	\$ 2,000,000
Debt discount	(151,097)
Debt issuance costs	(71,236)
Carrying value	\$ 1,777,667

5. Stockholders Equity

Equity Offerings

Edgar Filing: TREVENA INC - Form 10-Q

On September 16, 2015, the Company issued and sold 7,475,000 shares of common stock in a public offering at a price of \$9.75 per share, for gross proceeds of approximately \$72.9 million. The net offering proceeds to the Company from the combined sales were approximately \$68.4 million, after deducting underwriting discounts and commissions of approximately \$4.4 million and offering costs of \$0.1 million recognized through September 30, 2015.

On July 7, 2015, the Company issued and sold 1,000,000 shares of common stock through Cowen and Company, LLC (Cowen), pursuant to an at-the-market (ATM) sales facility dated April 3, 2015. The shares were sold at a weighted average price per share of \$6.0001, for aggregate gross proceeds of \$6.0 million. The net offering proceeds to the Company were approximately \$5.8 million after deducting related expenses, including commissions of approximately \$0.2 million.

On May 8, 2015, the Company issued and sold 2,700,000 shares of common stock through Cowen pursuant to the ATM facility at a weighted average price per share of \$6.2503, for aggregate gross proceeds of \$16.9 million. The net offering proceeds to the Company were approximately \$16.2 million after deducting related expenses, including commissions of approximately \$0.5 million.

Table of Contents**Equity Incentive Plans**

In 2008, the Company adopted the 2008 Equity Incentive Plan, as amended on February 29, 2008, January 7, 2010, July 8, 2010, December 10, 2010, June 23, 2011 and June 17, 2013 (collectively, the 2008 Plan) that authorized the Company to grant restricted stock and stock options to eligible employees, directors and consultants to the Company.

In 2013, the Company adopted the 2013 Equity Incentive Plan, as amended on May 14, 2014 and January 1, 2015 (collectively, the 2013 Plan). The 2013 Plan became effective upon the Company's entry into the underwriting agreement related to its initial public offering (IPO) in January 2014 and, as of such date, the Company may not make further grants under the 2008 Plan. The 2013 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of the Company. Additionally, the 2013 Plan provides for the grant of cash and stock based performance awards. The 2013 Plan contains an evergreen provision, pursuant to which the number of shares of common stock available for issuance under the plan will automatically increase on January 1 of each year beginning in 2015.

The estimated grant-date fair value of the Company's share-based awards is amortized ratably over the awards' service periods. Share-based compensation expense recognized was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	\$ 349,698	\$ 304,885	\$ 927,521	\$ 921,069
General and administrative	540,720	389,481	1,421,005	968,863
Total stock-based compensation	\$ 890,418	\$ 694,366	\$ 2,348,526	\$ 1,889,932

A summary of stock option activity for the nine months ended September 30, 2015 is as follows:

	Number of Shares	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Balance, December 31, 2014	3,574,450	\$	3.75	8.06
Granted	1,554,960		6.95	
Exercised	(317,681)		2.15	
Forfeitures/Expirations	(153,780)		6.04	
Balance, September 30, 2015	4,657,949	\$	4.85	8.08
Vested or expected to vest at September 30, 2015	4,500,954	\$	4.78	
Exercisable at September 30, 2015	1,830,274	\$	2.96	

Edgar Filing: TREVENA INC - Form 10-Q

The intrinsic value of the options exercisable as of September 30, 2015 was \$13.5 million, based on the Company's closing stock price of \$10.35 per share and a weighted average exercise price of \$2.96 per share.

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 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, 2015 and 2014 was estimated at \$4.37 and \$4.50 per share, respectively, using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2015	2014
Expected term of options (in years)	6.22	5.87
Risk-free interest rate	1.69%	1.82%
Expected volatility	69%	76%
Dividend yield	0%	0%

Table of Contents

The weighted-average valuation assumptions were determined as follows:

- **Risk-free interest rate:** The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- **Expected term of options:** Due to its lack of sufficient historical data, the Company estimates the expected life of its employee stock options using the simplified method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.
- **Expected stock price volatility:** The Company estimated the expected volatility based on actual historical volatility of the stock price of similar companies with publicly-traded equity securities. The Company calculated the historical volatility of the selected companies by using daily closing prices over a period of the expected term of the associated award. The companies were selected based on their enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected term of the associated award. A decrease in the selected volatility would have decreased the fair value of the underlying instrument.
- **Expected annual dividend yield:** The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in the continued growth of the business. Accordingly, the Company assumed an expected dividend yield of 0.0%.
- **Estimated forfeiture rate:** The Company's estimated annual forfeiture rate for the nine months ended September 30, 2015 and 2014 stock option grants was 9% and 7%, respectively, based on the historical forfeiture experience.

The fair value of the Company's common stock, prior to the IPO, was determined by its board of directors with assistance from its management. The board of directors and management considered numerous objective and subjective factors in the assessment of fair value, including the price for the Company's preferred stock that was sold to investors and the rights, preferences and privileges of the preferred stock and common stock, the Company's financial condition and results of operations during the relevant periods and the status of strategic initiatives. These estimates involved a significant level of judgment.

Edgar Filing: TREVENA INC - Form 10-Q

As of September 30, 2015, there was \$9.5 million of total unrecognized compensation expense related to unvested options that will be recognized over the weighted average remaining period of 2.90 years.

Shares Available for Future Grant

At September 30, 2015, the Company has the following shares available to be granted under the 2013 Plan:

Available at December 31, 2014	829,364
Authorized	1,569,646
Granted	(1,554,960)
Forfeitures/Expirations	153,780
Available at September 30, 2015	997,830

Shares Reserved for Future Issuance

At September 30, 2015, the Company has reserved the following shares of common stock for issuance:

Stock options outstanding	4,657,949
Shares available for future grant under 2013 Plan	997,830
Employee stock purchase plan	225,806
Warrants outstanding	27,839
	5,909,424

Table of Contents

6. Commitments and Contingencies

Licenses

On May 3, 2013, the Company entered into an option agreement and a license agreement with Allergan plc (formerly Actavis plc and Forest Laboratories Holdings Limited), under which the Company granted to Allergan an exclusive option to license its product candidate, TRV027. If Allergan exercises this option, the license agreement between the Company and Allergan will become effective and Allergan will have an exclusive worldwide license to develop and commercialize TRV027 and specified related compounds. At the Company's request, Allergan will consider in good faith whether to grant the Company the right to co-promote the licensed products in the United States under terms to be agreed upon by the parties. Allergan will be responsible for subsequent development, regulatory approval and commercialization of TRV027 at Allergan's sole cost and expense.

Under the option agreement, the Company is conducting, at its expense, a Phase 2b trial of TRV027 in acute heart failure, or AHF. In March 2015, Allergan and the Company signed a letter agreement wherein Allergan agreed to pay the Company \$10.0 million to fund the expansion of this ongoing Phase 2b trial of TRV027 from 500 patients to 620 patients. As part of this agreement, the Company and Allergan agreed to certain testing and analysis with respect to the study. The extended Phase 2b trial and related analysis are currently expected to be completed in the second quarter of 2016. Collaboration revenue will be recognized on a straight line basis over the study period. At the end of each reporting period, the Company will reassess the trial completion date and adjust the recognition period if necessary. The March 2015 letter agreement does not otherwise amend the terms of the May 2013 option agreement. Allergan may exercise its option during the pendency of the Phase 2b clinical trial or during a specified time period after the Company delivers the data from the Phase 2b clinical trial to Allergan. During the option period, the Company is not permitted to negotiate for or enter into any agreement with a third party for the development and commercialization of TRV027 and its related compounds. Under specified circumstances linked to adverse changes in the market or related to the results from the Phase 2b trial of TRV027, Allergan has the right to renegotiate the terms of the license agreement. If Allergan exercises such right, the Company will be obligated to negotiate in good faith with Allergan for a period of time the terms of any new arrangement. If the Company and Allergan are unable to agree on the terms of any new arrangement, then the option agreement will terminate and for a specified period of time thereafter the Company may not offer a license to any third party on terms better than those last proposed by either the Company or Allergan during the negotiations.

If Allergan does not exercise its option during the specified period, the option will expire and the license agreement will not become effective. In that case, the Company would be free to enter into a collaboration arrangement with another party for the development and commercialization of TRV027 or to pursue development and commercialization on its own. The Company received no consideration upon the grant of the option to Allergan. If Allergan exercises the option, the Company would receive a \$65.0 million option exercise fee and could potentially receive up to an additional \$365.0 million depending upon the achievement of future development and commercial milestones. The Company also could receive tiered royalties between 10% and 20% on net sales of licensed products worldwide, with the royalty rates on net sales of licensed products in the United States being somewhat higher than the royalty rates on net sales of licensed products outside the United States. The term of the royalty on sales of TRV027 for a given country would extend until the latest to occur of (i) 10 years from first commercial sale of TRV027 in that country, (ii) the expiration of the last to expire patent claiming TRV027 that is sufficient to block the entrance of a generic version of the product, or (iii) the expiration of any period of exclusivity granted by applicable law or any regulatory authority in such country that confers exclusive marketing rights on the product.

If the license agreement becomes effective, Allergan has the right to grant sublicenses under the license agreement to affiliates and third parties. Any sublicensing does not act to relieve Allergan of any of its obligations under the license agreement, including Allergan's obligation to make milestone payments to the Company with respect to TRV027 or pay royalties to the Company on sales of TRV027 by such sublicensee. Under the license, both Allergan and the Company have the right to terminate the agreement in the event of an uncured material breach or insolvency

of the other party. In addition, Allergan is permitted to terminate the license agreement without cause at any time upon prior written notice or immediately for product safety reasons. Following a termination of the license agreement, all licenses granted to Allergan would terminate, and Allergan would grant the Company an exclusive royalty-bearing license under specified patents and know-how to develop and commercialize reverted licensed products. If not terminated, the license agreement would remain in effect until the expiration of the last royalty term for the last licensed product.

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 or cash flows.

7. Revenue

For the three and nine months ended September 30, 2015, the Company recognized collaboration revenue of \$1.9 million and \$4.4 million, respectively, related to its March 2015 letter agreement with Allergan. The terms of this agreement contain multiple

Table of Contents

deliverables which include (i) research and development activities and (ii) testing and analysis related to the ongoing Phase 2b trial of TRV027 in exchange for a nonrefundable upfront fee of \$10.0 million. 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.

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 (ASU 2009-13), 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 judgement 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 arrangement. Whenever the Company determines that an element is delivered over a period of time, revenue is recognized using either a proportional 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.

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Basic and diluted net loss per common share calculation:				
Net loss and comprehensive loss	\$ (10,615,483)	\$ (15,534,872)	\$ (35,063,979)	\$ (36,403,967)
Accretion of redeemable convertible preferred stock				(28,521)
Net loss attributable to common stockholders	\$ (10,615,483)	\$ (15,534,872)	\$ (35,063,979)	\$ (36,432,488)
Weighted average common shares outstanding	44,214,428	26,366,300	41,443,362	23,036,366
Net loss per share of common stock - basic and diluted	\$ (0.24)	\$ (0.59)	\$ (0.85)	\$ (1.58)

The following outstanding securities at September 30, 2015 and 2014 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	September 30,	
	2015	2014
Options outstanding	4,657,949	3,552,124

Edgar Filing: TREVENA INC - Form 10-Q

Warrants	27,839	30,258
Total	4,685,788	3,582,382

Table of Contents

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 2014 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Overview

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

- *Oliceridine (TRV130)*: In October 2015, we announced that the United States Adopted Name (USAN) approved name for TRV130 is oliceridine. We are developing oliceridine as a first-line treatment for patients experiencing moderate to severe acute pain where IV administration is preferred. In August 2015, we announced results from a second Phase 2 trial of oliceridine in acute postoperative pain, as further described below. We hold a U.S. patent (U.S. Patent No. 8,835,488) covering the composition of matter and methods of use for oliceridine. We have retained all worldwide development and commercialization rights to oliceridine, and plan to commercialize it in the United States for use in acute care settings such as hospitals and ambulatory surgery centers if it receives regulatory approval.
- *TRV027*: We are developing TRV027 for the treatment of acute heart failure, or AHF. In early 2014 we initiated a Phase 2b clinical trial of TRV027 (BLAST-AHF) for the treatment of AHF. In January 2015, we conducted a planned interim analysis, evaluating data from approximately 250 patients in this trial. Upon reviewing the data, the data safety monitoring board, or DSMB, and the BLAST-AHF Steering Committee recommended that future enrollment be weighted to the most promising dose of 5 mg/hr. We announced in March 2015 that remaining enrollment will be weighted 2:1:2:1 to placebo, 1 mg/hr, 5 mg/hr, and 25 mg/hr, respectively, and that we have increased target enrollment in the study from 500 patients to 620 patients. In addition, the DSMB and Steering Committee determined that patients with lower baseline systolic blood pressure could safely enroll in the study; inclusion criteria have been modified accordingly. Allergan plc, or Allergan, which holds an exclusive option to license TRV027, has fully funded this expansion of the study via a \$10.0 million payment to us to defray the external and internal costs of increasing the study sample size. As of October 21, 2015, 446 patients have been enrolled in the study. The most recent DSMB review of the study was conducted in October 2015 and recommended that the study continue without modification. We expect to release top-line data from the BLAST-AHF trial in the second quarter of 2016.
- *TRV250*: We are developing TRV250, a G protein biased ligand targeting the delta receptor, as a compound with potential first-in-class mechanism for the treatment of migraine. TRV250 also may have utility in a range of other central nervous system indications, and based on target selectivity it is not expected to have the addiction

liability of mu opioid drugs like morphine or oxycodone. We have initiated preclinical development activities to support our submission of an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or FDA, in 2016.

In addition to the above three product candidates, we identified and have completed the Phase 1 program for TRV734, an orally administered clinical compound 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 worldwide development and commercialization partner for this asset. The U.S. patent covering the composition of matter and methods of use for TRV734 was issued in June 2015 (U.S. Patent No. 9,044,469), and we hold all worldwide development and commercialization rights to 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 September 30, 2015, we had an accumulated deficit of \$167.0 million. Our net loss was \$35.1 million and \$36.4 million for the nine months ended September 30, 2015 and 2014, respectively. Our ability to become and remain profitable depends on our ability to generate revenue or sales. We do not expect to generate significant revenue or sales unless and until we or a collaborator obtain marketing approval for and commercialize oliceridine, TRV027, TRV250 or TRV734.

In September 2014, we announced we had entered into a \$35.0 million senior secured tranching term loan credit facility with Oxford Finance LLC and Square 1 Bank, of which we have drawn \$2.0 million as of September 30, 2015. The facility also provides for up to two additional term loan tranches of \$16.5 million each. Based on the top-line results of the Phase 2a/b clinical trial of oliceridine announced in November 2014, we have met the conditions to draw the \$16.5 million second tranche under the credit facility and may draw this between October 1, 2015 and December 31, 2015. We may opt to draw the third term loan tranche if we receive positive data from the Phase 2 clinical trial of TRV027 before March 31, 2016.

Table of Contents

We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses. Furthermore, following our IPO in January 2014, we have incurred and expect to continue to incur significant legal, accounting, investor relations and other costs associated with operating as a public company. We will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. 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 the development and/or commercialization of one or more of our product candidates.

Oliceridine (TRV130)

We have completed two Phase 2 clinical trials of oliceridine (TRV130) and we expect to initiate a Phase 3 clinical program for oliceridine in the first quarter of 2016. We will discuss our Phase 3 plans with the FDA at an End of Phase 2 (EoP2) meeting, which we expect to occur in the first quarter of 2016. At the EoP2 meeting, we will discuss the design and conduct of two adequate and well-controlled clinical studies – one in patients after bunionectomy surgery, and one in patients after abdominoplasty surgery – in which we expect a total of between 300 and 600 patients to be exposed to oliceridine. We expect to begin these studies in the second quarter of 2016. Based on recent draft guidance from the FDA on the development of analgesic drug products, we believe that these two studies, plus additional Phase 3 studies in which approximately 600 to 900 additional patients would be exposed to oliceridine will be sufficient for the FDA to review a new drug application, or NDA, for oliceridine. Assuming FDA’s concurrence with these plans, we expect that top-line data from the pivotal trials will be available in the first quarter of 2017. If these trials are successful, we expect to submit an NDA for oliceridine to the FDA in the second half of 2017.

Phase 2b abdominoplasty study

In August 2015, we announced results from our randomized, double-blind, placebo- and active-controlled Phase 2b trial of oliceridine in moderate to severe postoperative pain after abdominoplasty surgery. In the trial, two regimens of oliceridine were tested: the first consisted of a 1.5 mg intravenous loading dose with 0.1 mg self-administered on-demand doses as often as every 6 minutes using a patient controlled analgesia (PCA) device; the second consisted of a 1.5 mg loading dose with 0.35 mg on-demand doses using a PCA device. A commonly used morphine PCA regimen also was tested, consisting of a 4 mg loading dose with 1 mg on-demand doses. Placebo was administered as a loading dose and on-demand doses that were volume-matched to the active regimens.

The Phase 2b trial achieved its primary endpoint of statistically greater pain reduction than placebo over 24 hours. In addition, oliceridine was superior to morphine in pre-specified secondary measures, exhibiting a significantly lower prevalence (percentage of patients) of hypoventilation events (a measure of respiratory safety), nausea, and vomiting than the morphine group (post hoc $p < 0.05$ for both oliceridine regimens vs. morphine). Adverse events associated with oliceridine were largely opioid-related; the most frequently reported events were nausea, vomiting, hypoventilation and headache. Opioid-related adverse events were generally less frequent in the oliceridine groups compared to morphine. No drug-related serious adverse events were reported in the study.

Phase 2a/b bunionectomy study

Edgar Filing: TREVENA INC - Form 10-Q

In November 2014, we announced top-line data from our Phase 2a/b clinical trial of oliceridine in postoperative pain following bunionectomy surgery. At doses of 2 mg and 3 mg of oliceridine administered every three hours, the bunionectomy trial achieved its primary endpoint of statistically greater pain reduction than placebo for 48 hours, which we believe demonstrates proof of concept for oliceridine. The 3 mg dose of oliceridine also showed statistically superior analgesic efficacy over the 48-hour trial period compared to 4 mg of morphine administered every four hours. There were no serious adverse events reported in the trial, which we believe suggests that these levels of pain relief can be achieved safely.

Option and License Agreements with Allergan plc

On May 3, 2013, we entered into an option agreement and a license agreement with Allergan plc (formerly Actavis plc and Forest Laboratories Holdings Limited), under which we granted to Allergan an exclusive option to license TRV027. If Allergan exercises this option, the license agreement will become effective and Allergan will have an exclusive worldwide license to develop and commercialize TRV027 and specified related compounds. Allergan will be responsible for subsequent development, regulatory

Table of Contents

approval and commercialization of TRV027 at Allergan's expense. At our request, Allergan will consider in good faith whether to grant us the right to co-promote the licensed products in the United States under terms to be agreed upon by the parties, but Allergan has no obligation to grant us such right.

Under the option agreement, we will conduct, at our expense, a Phase 2b clinical trial of TRV027 in AHF. Allergan may exercise its option at any time during the Phase 2b clinical trial or during a specified time period after we deliver the data from the Phase 2b clinical trial to Allergan. During the option period, we are not permitted to negotiate for or enter into any agreement with a third party for the development and commercialization of TRV027 and its related compounds. Under specified circumstances linked to adverse changes in the market or related to the results from the Phase 2b clinical trial of TRV027, Allergan has the right to renegotiate the terms of the license agreement. If Allergan exercises such right, we will be obligated to negotiate in good faith with Allergan for a period of time the terms of any new arrangement. If we and Allergan are unable to agree on the terms of any new arrangement, then the option agreement will terminate and for a specified period of time thereafter we may not offer a license to any third party on terms better than those last proposed by either us or Allergan during the negotiations. If Allergan does not exercise its option during the specified period, the option will expire and the license agreement will not become effective. In that case, we would be free to enter into a collaboration arrangement with another party for the development and commercialization of TRV027 or to pursue development and commercialization on our own.

We received no consideration upon the grant of the option to Allergan. In March 2015, Allergan and we signed a letter agreement wherein Allergan agreed to pay \$10.0 million to fund the expansion of the ongoing Phase 2b trial from 500 patients to 620 patients. The \$10.0 million received in March 2015 was recorded as deferred revenue. The collaboration revenue will be recorded on a straight-line basis through the expected term of the trial. The March 2015 letter agreement does not otherwise amend the terms of the May 2013 option agreement. If Allergan exercises the option, we would receive a \$65.0 million option exercise fee and could potentially receive up to \$365.0 million in additional payments depending upon the achievement of future development and commercial milestones. We also could receive tiered royalties between 10% and 20% on net sales of licensed products worldwide, subject to specified deductions and offsets, with the royalty rates on net sales of licensed products in the United States being somewhat higher than the royalty rates on net sales of licensed products outside the United States. The term of the royalty on sales of TRV027 for a given country would extend until the latest to occur of (i) ten years from first commercial sale of TRV027 in that country, (ii) the expiration of the last to expire patent claiming TRV027 that is sufficient to block the entrance of a generic version of the product, or (iii) the expiration of any period of exclusivity granted by applicable law or any regulatory authority in such country that confers exclusive marketing rights on the product.

If the license agreement becomes effective, Allergan has the right to grant sublicenses under the license agreement to affiliates and third parties. Any sublicensing does not relieve Allergan of any of its obligations under the license agreement, including Allergan's obligation to make milestone payments to us with respect to TRV027 or pay royalties to us on sales of TRV027 by such sublicensee. Under the license, both we and Allergan have the right to terminate the agreement in the event of an uncured material breach or insolvency of the other party. In addition, Allergan is permitted to terminate the license agreement without cause at any time upon prior written notice or immediately for product safety reasons. Following a termination of the license agreement, all licenses granted to Allergan would terminate, and Allergan would grant to us an exclusive royalty-bearing license under specified patents and know-how to develop and commercialize reverted licensed products. If not terminated, the license agreement would remain in effect until the expiration of the last royalty term for the last licensed product.

Senior Secured Tranched Term Loan Credit Facility

In September 2014, we entered into a loan and security agreement with Oxford Finance LLC and Square 1 Bank, or the lenders, pursuant to which they have agreed to lend us up to \$35.0 million in a three-tranche series of term loans. Upon initially entering into the agreement, we borrowed \$2.0 million. On April 13, 2015, we amended the agreement with the lenders to change the draw period for Term Loan B. As amended, we may now, at our sole discretion, borrow from the lenders:

- \$16.5 million, at any time beginning on October 1, 2015 and ending on December 31, 2015, since we have satisfied specified conditions precedent related to the results of our Phase 2 bunionectomy trial of oliceridine (TRV130); and
- an additional \$16.5 million, at any time on or before March 31, 2016, subject to the satisfaction of specified conditions related to the results of our Phase 2b clinical trial of TRV027.

Borrowings accrue interest at a fixed rate of 6.50% per annum. We are required to make payments of interest only on borrowings under this agreement on a monthly basis through and including April 1, 2016, which we refer to as the interest only termination date extended from October 1, 2015, since we have satisfied specified conditions precedent related to the results of our recently concluded Phase 2 bunionectomy study of oliceridine after which payments of principal in equal monthly installments and

Table of Contents

accrued interest will be due until the loan matures on December 1, 2018. Both the interest only termination date and the maturity date may be further modified as follows if we meet the conditions related to the Phase 2b trial of TRV027 by March 31, 2016:

- the interest only termination date will be extended until October 1, 2016, and
- the maturity date will be extended to September 1, 2019 if we have received net cash proceeds of at least \$50.0 million from our existing option and license with Allergan or another strategic partnership satisfactory to the lenders.

We paid the lenders a facility fee of \$175,000 in connection with the execution of the agreement. Upon the last payment date of the amounts borrowed under the agreement, we will be required to pay a final payment fee ranging from 6.1% to 7.0% of the aggregate amounts borrowed. In addition, if we repay the borrowings prior to the maturity date, we will be obligated to pay a prepayment fee of 3.0% of the total amount prepaid if the prepayment occurs prior to the first anniversary of the funding of the applicable tranche, 2.0% percent of the total amount prepaid if the prepayment occurs between the first and second anniversary of the funding of the applicable tranche, and 1.0% of the total amount prepaid if the prepayment occurs on or after the second anniversary of the funding of the applicable tranche.

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.

We used a placement agent in connection with the agreement. We paid the agent \$65,000 upon execution of the agreement and will be obligated to pay up to an additional \$175,000 if we draw on the second and third tranches.

In connection with entering into the agreement, we issued to the lenders warrants to purchase an aggregate of 7,678 shares of our common stock. 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. If we draw on the second or third tranches, we will issue additional warrants to purchase shares of our common stock, each with an exercise price of \$5.8610 per share and on substantially the same terms as those contained in the initial warrants. The number of shares underlying these additional warrants will depend on the amount of additional borrowings we make, but will not exceed 126,684.

Components of Operating Results

Revenue

To date, we have derived revenue principally from research grants and collaboration arrangements. In March 2015, Allergan and we signed a letter agreement wherein Allergan agreed to pay us \$10.0 million to fund the expansion of an ongoing Phase 2b trial of TRV027 from 500 patients to 620 patients. The payment was recorded as deferred revenue and will be recognized on a straight-line basis through the expected term of the trial.

We have not generated any revenue from commercial product sales. In the future, if any of our product candidates currently under development is approved for commercial sale, we may generate revenue from product sales, or alternatively, we may choose to select a collaborator to commercialize our product candidates in all or selected markets.

General and Administrative Expenses

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.

Research and Development Expenses

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 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.

Table of Contents

Other Income (Expense)

A warrant to purchase up to 20,161 shares of the Company's common stock is outstanding with a fair value recorded as a liability of \$153,953 at September 30, 2015, as it contains a cash settlement feature upon certain strategic transactions. The change in the fair value of the warrant liability is estimated using the Black-Scholes option pricing model and adjustments are recorded in the Statements of Operations.

Other income consists principally of interest income earned on cash and cash equivalent balances, marketable securities and miscellaneous income attributable to the sale of research and development tax credits.

Interest expense consists of interest related to our outstanding loan.

Recent Accounting Pronouncements

On April 7, 2015, the FASB issued Accounting Standards Update 2015-03, Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03). ASU 2015-03 requires debt issuance costs to be presented in the balance sheets as a direct deduction from the associated debt liability. Although the standard is retrospectively effective for annual reporting periods beginning after December 15, 2015, early adoption is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued. We elected early adoption during the first quarter of 2015 that resulted in a balance sheet adjustment as of December 31, 2014 of \$98,401 to other assets and loans payable, net. Our adoption of this standard did not have a significant impact on our results of operations or cash flows.

In May 2014, the FASB issued Accounting Standards Update 2014-09 Revenue from Contracts with Customers (ASU 2014-09). 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. In July 2015, the FASB decided to defer the effective date of the standard from January 1, 2017, to January 1, 2018, with an option that permits companies to adopt the standard as early as the original effective date. Early application prior to the original effective date is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The adoption of this standard is not expected to have a material impact on our financial statements.

JOBS Act

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 not to 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 Nine Months Ended September 30, 2015 and 2014*

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	Change	2015	2014	Change
Revenue:						
Collaboration revenue	\$ 1,875,000	\$	\$ 1,875,000	\$ 4,375,000	\$	\$ 4,375,000
Total revenue	1,875,000		1,875,000	4,375,000		4,375,000
Operating expenses:						
General and administrative	2,780,115	2,536,807	243,308	8,977,000	7,033,492	1,943,508
Research and development	9,650,138	13,006,568	(3,356,430)	30,524,601	29,671,114	853,487
Total operating expenses	12,430,253	15,543,375	(3,113,122)	39,501,601	36,704,606	2,796,995
Loss from operations	(10,555,253)	(15,543,375)	4,988,122	(35,126,601)	(36,704,606)	1,578,005
Other income (expense):						
Change in fair value of warrant liability	(68,037)	11,181	(79,217)	(71,102)	109,522	(180,623)
Gain on asset disposal				2,656		2,656
Miscellaneous income	731		730	174,266	184,015	(9,750)
Interest income	79,407	1,809	77,598	172,095	11,589	160,506
Interest expense	(72,331)	(4,487)	(67,844)	(215,293)	(4,487)	(210,806)
Total other income (expense)	(60,230)	8,503	(68,733)	62,622	300,639	(238,017)
Net loss and comprehensive loss	(10,615,483)	(15,534,872)	4,919,389	(35,063,979)	(36,403,967)	1,339,988
Accretion of preferred stock					(28,521)	28,521
Net loss attributable to common stockholders	\$ (10,615,483)	\$ (15,534,872)	\$ 4,919,389	\$ (35,063,979)	\$ (36,432,488)	\$ 1,368,509

Table of Contents*Revenue*

Collaboration revenue increased \$1.9 million and \$4.4 million for the three and nine months ended September 30, 2015, respectively, as compared to the same periods in 2014 due to our entry into a letter agreement with Allergan on March 5, 2015. Under this agreement, Allergan paid us \$10.0 million, which was recorded as deferred revenue, to fund the expansion of the ongoing Phase 2b trial of TRV027 from 500 patients to 620 patients. The collaboration revenue will be recognized on a straight-line basis through the expected term of the trial.

General and administrative expense

General and administrative expenses increased by \$0.2 million, or 10%, and \$1.9 million, or 28%, for the three and nine months ended September 30, 2015, respectively, compared to the same periods in 2014 primarily as a result of increased headcount and associated salary, bonus and stock compensation expenses, recruiting fees and market research expenditures.

Research and development expense

Research and development expenses decreased by \$3.4 million, or 26%, and increased by \$0.9 million, or 3%, for the three and nine months ended September 30, 2015, respectively, compared to the same periods in 2014. The following table summarizes our research and development expenses:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
TRV027 (external costs)	\$ 3,313,240	\$ 3,179,180	\$ 7,340,452	\$ 8,421,116
Oliceridine (TRV130) (external costs)	2,895,024	5,684,105	12,764,836	10,581,769
Stock-based compensation	349,698	304,885	927,521	921,069
Other personnel-related costs	1,904,922	1,416,141	5,794,772	4,143,075
Other research and development	1,187,254	2,422,257	3,697,020	5,604,085
	\$ 9,650,138	\$ 13,006,568	\$ 30,524,601	\$ 29,671,114

The decrease for the three months ended September 30, 2015 was primarily due to reduced expenditures associated with the Phase 2a/b bunionectomy study of oliceridine (TRV130), which completed enrollment in December 2014, and the Phase 1 multiple ascending dose clinical study of TRV734, which completed enrollment in November 2014, partially offset by increased expenditures associated with the Phase 2b abdominoplasty study of oliceridine which started enrollment in December 2014 and completed enrollment in July 2015. The slight increase for the nine months ended September 30, 2015 was primarily driven by increased expenditures associated with the Phase 2b abdominoplasty study of oliceridine, personnel-related costs, and oliceridine pharmaceutical development expenses, partially offset by decreases in expenditures associated with (i) the Phase 2a/b bunionectomy study of oliceridine, (ii) the Phase 2b clinical trial of TRV027 and (iii) the Phase 1 program for TRV734.

Interest income

Interest income for the periods presented reflects interest income earned on balances in cash and cash equivalents and marketable securities.

Interest expense

We recorded interest expense of \$72,331 and \$215,923 during the three and nine months ended September 30, 2015, consisting of cash paid and non-cash interest expense related to our loan originating in September 2014.

Liquidity and Capital Resources

We incurred net losses of \$35.1 million and \$36.4 million for the nine months ended September 30, 2015 and 2014, respectively. Net cash used in operating activities was \$28.2 million and \$26.7 million during the nine months ended September 30, 2015 and 2014, respectively. At September 30, 2015, we had an accumulated deficit of \$167.0 million, working capital of \$159.3 million, cash and cash equivalents of \$39.0 million and marketable securities of \$129.9 million. Prior to our IPO, we financed our operations principally through private placements of preferred stock. In February 2014, we completed our IPO, in December 2014 and September 2015 we completed underwritten follow-on offerings of common stock, and in July 2015 and May 2015 we sold shares of common stock through Cowen and Company, LLC, or Cowen, pursuant to an at-the-market, or ATM, sales facility (see Operating and Capital Expenditure Requirements below).

Table of Contents**Cash Flows**

The following table summarizes our cash flows for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,	
	2015	2014
Net cash (used in) provided by:		
Operating activities	\$ (28,223,478)	\$ (26,729,773)
Investing activities	(60,139,329)	(421,517)
Financing activities	91,191,957	61,410,649
Net increase in cash and cash equivalents	\$ 2,829,150	\$ 34,259,359

Net cash used in operating activities

Net cash used in operating activities was \$28.2 million for the nine months ended September 30, 2015, consisting primarily of a net loss of \$35.1 million partially offset by noncash adjustments of \$3.5 million and changes in operating assets and liabilities of \$3.4 million. Changes in operating assets and liabilities were primarily driven by an increase of deferred revenue of \$5.6 million associated with the payment received from Allergan in March 2015 partially offset by an increase in prepaid expenses and other assets of \$0.3 million and a decrease in accounts payable and accrued expenses of \$1.9 million.

Net cash used in operating activities was \$26.7 million for the nine months ended September 30, 2014 and consisted primarily of a net loss of \$36.4 million partially offset by noncash adjustments of \$2.0 million and changes in operating assets and liabilities of \$7.7 million. The noncash adjustments were primarily attributable to increased expense associated with stock options granted and depreciation and amortization related to leasehold improvements and capital equipment partially offset by a gain recognized on the revaluation of the warrant liability. Changes in operating assets and liabilities were driven by a decrease in prepaid expenses and other assets of \$3.0 million and an increase in accounts payable and accrued expenses of \$4.7 million. The decrease in prepaid expenses and other assets was primarily due to prepaid IPO costs incurred in 2013 partially offset by prepaid expenses in 2014 related to the startup of the Phase 2b trial for TRV027 and Phase 2a/b study for oliceridine (TRV130). The increase in accounts payable and accrued expenses was primarily due to the timing and volume of our payment of costs related to ongoing development of our product candidates.

Net cash used in investing activities

Net cash used in investing activities for the nine months ended September 30, 2015 was \$60.1 million and was due primarily to the investment of proceeds from our common stock sales and offering into marketable securities partially offset by cash received from maturities of our marketable securities. Both periods presented also include expenditures related to leasehold improvements and the purchase of capital equipment.

Net cash provided by financing activities

Net cash provided by financing activities was \$91.2 million for the nine months ended September 30, 2015, which was primarily due to net proceeds of \$68.5 million from the public offering of common stock and net proceeds of \$22.0 million from the sale of common stock through Cowen pursuant to the ATM sales facility.

Net cash provided by financing activities was \$61.4 million for the nine months ended September 30, 2014, which was primarily due to net proceeds from the issuance of common stock in our initial public offering.

Both periods presented also include 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 increase in the near term as we fund our ongoing Phase 2 clinical trial of TRV027, prepare for and launch future Phase 3 clinical trials of oliceridine (TRV130), and continue preclinical 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 sales and marketing of any future products.

Table of Contents

We believe that our cash and cash equivalents and marketable securities as of September 30, 2015, together with interest thereon, will be sufficient to fund our operating expenses and capital expenditure requirements into 2018. However, we anticipate that we will need to raise substantial additional financing in the future to fund our operations in 2018 and beyond. 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 April 2015, we filed a \$150 million shelf registration statement that includes a \$40 million ATM sales facility with Cowen acting as our sales agent. Since then, we have sold approximately 10.2 million shares of our common stock under this registration statement, generating net proceeds of approximately \$90.5 million. There remains approximately \$54.2 million of available capacity under the registration statement, including approximately \$17.1 million that may be sold under the ATM facility. We may offer and sell additional 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.

In addition to potential equity and convertible financings, we have the option during the fourth quarter of 2015 to draw \$16.5 million under our existing loan and security agreement with Oxford Finance LLC and Square 1 Bank, since we have satisfied specified conditions precedent related to the results of our Phase 2 bunionectomy trial of oliceridine. Subject to the satisfaction of specified conditions related to the results of our Phase 2b clinical trial of TRV027 on or before March 31, 2016, we also will have the option to draw an additional \$16.5 million under this loan and security agreement.

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 ongoing Phase 2 clinical program for TRV027 and the planned Phase 3 clinical program for oliceridine;
- whether Allergan exercises its option to license TRV027;
- our ability to enter into collaborative agreements for the development and commercialization of our product candidates, for example TRV734;
- the number and development requirements of any other product candidates that we 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;

Edgar Filing: TREVENA INC - Form 10-Q

- 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 our most recent Annual Report on Form 10-K as filed with the SEC and which are incorporated herein by reference, for additional risks associated with our substantial capital requirements.

Table of Contents

Option and License Agreements and Other Commitments

For a description of our agreement with Allergan, see [Option and License Agreement with Allergan plc](#) above.

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 could also enter into additional collaborative research, contract research, manufacturing and supplier agreements in the future, which may require upfront payments and even long-term commitments of cash.

Critical Accounting Policies and Significant Judgments and Estimates

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

Please see the [Critical Accounting Policies and Significant Judgments and Estimates](#) section of our most recent Annual Report on Form 10-K as filed with the SEC and which is incorporated herein by reference, for full detail. We have not made any significant changes to our critical accounting policies during the current quarter.

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

Not applicable to smaller reporting companies.

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 September 30, 2015, 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.

Table of Contents

PART II

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

There have been no material changes in our risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

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

(a) Sales of Unregistered Securities

During the nine months ended September 30, 2015, we have not sold any shares of unregistered securities.

(b) Use of Proceeds from Sales of Registered Securities

There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

Table of Contents

ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Quarterly Report on Form 10-Q. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit Number	Description
10.1+	Executive Employment Agreement effective as of July 20, 2015 by and between Trevena, Inc. and Yacoub Habib (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on July 21, 2015).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	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.
101*	The following financial information from this Quarterly Report on Form 10-Q for the periods ended September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets as of September 30, 2015 and December 31, 2014, (ii) Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014, (iii) Statement of Stockholders' Equity as of September 30, 2015, (iv) Statements of Cash Flows for the nine months ended September 30, 2015 and 2014 and (v) Notes to Financial Statements, tagged as blocks of text.

* Filed herewith.

+ Indicates management contract or compensatory plan.

Table of Contents

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: November 10, 2015

TREVENA, INC.

By:

/s/ ROBERTO CUCA
Roberto Cuca
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	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.
101	The following financial information from this Quarterly Report on Form 10-Q for the periods ended September 30, 2015, formatted in XBRL(eXtensible Business Reporting Language): (i) Balance Sheets as of September 30, 2015 and December 31, 2014, (ii) Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014, (iii) Statement of Stockholders Equity as of September 30, 2015, (iv) Statements of Cash Flows for the nine months ended September 30, 2015 and 2014 and (v) Notes to Financial Statements, tagged as blocks of text.

+ Indicates management contract or compensatory plan.