

TREVENA INC
Form 10-Q
May 05, 2016
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 March 31, 2016

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.:

Edgar Filing: TREVENA INC - Form 10-Q

Large accelerated filer

Accelerated filer

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 May 2, 2016: 52,174,299

Table of Contents

TABLE OF CONTENTS

	Page
<u>Cautionary Note Regarding Forward-Looking Statements</u>	2
<u>PART I- FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	
<u>Financial Statements (unaudited)</u>	3
<u>Balance Sheets</u>	3
<u>Statements of Operations and Comprehensive Income (Loss)</u>	4
<u>Statement of Stockholders' Equity</u>	5
<u>Statements of Cash Flows</u>	6
<u>Notes to Unaudited Financial Statements</u>	7
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	25
<u>Item 4.</u>	
<u>Controls and Procedures</u>	26
<u>PART II- OTHER INFORMATION</u>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	26
<u>Item 1A.</u>	
<u>Risk Factors</u>	26
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
<u>Item 3.</u>	
<u>Defaults Upon Senior Securities</u>	28
<u>Item 4.</u>	
<u>Mine Safety Disclosures</u>	28
<u>Item 5.</u>	
<u>Other Information</u>	28
<u>Item 6.</u>	
<u>Exhibits</u>	28
<u>SIGNATURES</u>	29

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 and likelihood of obtaining and maintaining regulatory approvals for our product candidates;
- the extent of clinical trials potentially required by the FDA for our product candidates;
- the clinical utility and market acceptance of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;

- our intellectual property position; and
- our ability to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives.

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

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

	March 31, 2016		December 31, 2015
	(unaudited)		
Assets			
Current assets:			
Cash and cash equivalents	\$ 34,452,266	\$	46,773,566
Marketable securities	129,016,409		125,864,447
Prepaid expenses and other current assets	2,486,566		1,892,217
Total current assets	165,955,241		174,530,230
Property and equipment, net	823,515		696,280
Restricted cash	112,620		112,620
Intangible asset, net	14,375		14,844
Total assets	\$ 166,905,751	\$	175,353,974
Liabilities and stockholders equity			
Current liabilities:			
Accounts payable	\$ 3,980,488	\$	6,749,625
Accrued expenses and other current liabilities	3,636,896		3,029,782
Deferred revenue	1,875,000		3,750,000
Deferred rent	45,996		43,907
Total current liabilities	9,538,380		13,573,314
Loans payable, net	18,219,788		18,185,898
Capital leases, net of current portion	14,312		7,942
Deferred rent, net of current portion	226,918		238,917
Warrant liability	111,751		153,238
Other long term liabilities	167,575		63,200
Total liabilities	28,278,724		32,222,509
Commitments and contingencies (Note 6)			
Stockholders equity:			
Common stock \$0.001 par value; 100,000,000 shares authorized, 52,170,958 and 50,802,603 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	52,171		50,802
Preferred stock \$0.001 par value; 5,000,000 shares authorized, none issued or outstanding			
Additional paid-in capital	338,821,662		325,784,484
Accumulated deficit	(200,276,944)		(182,497,965)
Accumulated other comprehensive income (loss)	30,138		(205,856)
Total stockholders equity	138,627,027		143,131,465
Total liabilities and stockholders equity	\$ 166,905,751	\$	175,353,974

See accompanying notes to financial statements.

Table of Contents

TREVENA, INC.

Statements of Operations and Comprehensive Income (Loss) (Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenue:		
Collaboration revenue	\$ 1,875,000	\$ 625,000
Total revenue	1,875,000	625,000
Operating expenses:		
General and administrative	3,917,750	3,089,622
Research and development	15,753,087	10,598,993
Total operating expenses	19,670,837	13,688,615
Loss from operations	(17,795,837)	(13,063,615)
Other income (expense):		
Change in fair value of warrant liability	41,487	(8,413)
Miscellaneous income	221,402	173,535
Interest income	193,134	39,469
Interest expense	(439,165)	(70,621)
Total other income	16,858	133,970
Net loss attributable to common stockholders	\$ (17,778,979)	\$ (12,929,645)
Other comprehensive income, net:		
Change in unrealized gains on marketable securities	235,994	26,757
Other comprehensive income	235,994	26,757
Comprehensive loss	\$ (17,542,985)	\$ (12,902,888)
Per share information:		
Net loss per share of common stock, basic and diluted	\$ (0.35)	\$ (0.33)
Weighted average common shares outstanding, basic and diluted	51,350,365	39,251,184

See accompanying notes to financial statements.

Table of Contents

TREVENA, INC.

Statement of Stockholders Equity (Unaudited)

For the period from January 1, 2016 to March 31, 2016

	Common Stock		Stockholders Equity			Total Stockholders Equity
	Number of Shares	\$0.001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	
Balance, January 1, 2016	50,802,603	\$ 50,802	\$ 325,784,484	\$ (182,497,965)	\$ (205,856)	\$ 143,131,465
Stock-based compensation expense			1,202,726			1,202,726
Exercise of stock options	17,600	18	39,856			39,874
Issuance of common stock, net of issuance costs	1,350,755	1,351	11,794,596			11,795,947
Unrealized gain on marketable securities					235,994	235,994
Net loss				(17,778,979)		(17,778,979)
Balance, March 31, 2016	52,170,958	\$ 52,171	\$ 338,821,662	\$ (200,276,944)	\$ 30,138	\$ 138,627,027

See accompanying notes to financial statements.

Table of Contents

TREVENA, INC.

Statements of Cash Flows (Unaudited)

	Three Months Ended March 31,	
	2016	2015
Operating activities:		
Net loss	\$ (17,778,979)	\$ (12,929,645)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	57,520	52,503
Stock-based compensation	1,202,726	613,887
Noncash interest expense on loans	138,264	37,909
Revaluation of warrant liability	(41,487)	8,413
Amortization of bond premium on marketable securities	417,628	
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(594,349)	(840,710)
Accounts payable and accrued expenses	(2,173,561)	(2,351,995)
Deferred revenue	(1,875,000)	9,375,000
Net cash used in operating activities	(20,647,238)	(6,034,638)
Investing activities:		
Purchase of property and equipment	(175,341)	(89,389)
Maturities of marketable securities	23,944,000	
Purchase of marketable securities	(27,277,595)	(1,124,420)
Net cash used in investing activities	(3,508,936)	(1,213,809)
Financing activities:		
Proceeds from exercise of common stock options	39,874	179,408
Proceeds from issuance of common stock, net	11,795,947	
Capital lease payments	(947)	(625)
Net cash provided by financing activities	11,834,874	178,783
Net decrease in cash and cash equivalents	(12,321,300)	(7,069,664)
Cash and cash equivalents beginning of period	46,773,566	36,205,559
Cash and cash equivalents end of period	\$ 34,452,266	\$ 29,135,895
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 300,901	\$ 32,712
Capital lease additions	\$ 8,944	\$

See accompanying notes to financial statements.

Table of Contents

TREVENA, INC.

Notes to Unaudited Financial Statements

March 31, 2016

1. Organization and Description of the Business

Trevena, Inc. (the Company) was incorporated in Delaware as Parallax Therapeutics, Inc. on November 9, 2007. The Company began operations in December 2007, and its name was changed to Trevena, Inc. on January 3, 2008. The Company is a 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 March 31, 2016, the Company had an accumulated deficit of \$200.3 million. The Company's net loss was \$17.8 million and \$12.9 million for the three months ended March 31, 2016 and 2015, respectively. The Company expects its cash and cash equivalents of \$34.5 million and marketable securities of \$129.0 million as of March 31, 2016, 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's functional currency is the U.S. dollar.

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 March 31, 2016 and the results of its operations, its comprehensive income (loss) and its cash flows for the three months ended March 31, 2016 and 2015. The financial data and other information disclosed in these notes related to the three months ended March 31, 2016 and 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2016, any other interim periods or any future year or period.

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, 2015. 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 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-

Table of Contents

classified common stock warrants, and the accounting for research and development costs, accrued expenses and the recoverability of the Company's net deferred tax assets and related valuation allowance.

Cash, Cash Equivalents, Investments and Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents, marketable securities and restricted cash. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk.

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents are valued at cost, which approximates their fair market value. The Company maintains a portion of its cash and cash equivalent balances in money market mutual funds that invest substantially all of their assets in U.S. government agency securities, U.S. Treasury securities and reverse repurchase agreements (RRAs). RRAs are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their value. The Company does not record an asset or liability related to the collateral, as the Company is not permitted to sell or repledge the associated collateral.

The Company maintains its marketable securities balances in the form of U.S. Treasury and U.S. government agency securities. The Company classifies its marketable securities as available-for-sale, pursuant to ASC Topic 320, *Investments - Debt and Equity Securities*, 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. As of March 31, 2016 and December 31, 2015, the Company had \$129.0 million and \$125.9 million, respectively, in available-for-sale investments, all classified as current assets. See Note 3 for additional information.

The fair value of our investments is determined based on observable market quotes or valuation models using assessments of counterparty credit worthiness, credit default risk of underlying security and overall capital market liquidity. The company reviews unrealized losses associated with available-for-sale securities to determine the classification as temporary or other-than-temporary impairment. A temporary impairment results in an unrealized loss being recorded in other comprehensive income (loss). If a decline in the fair value is considered other-than-temporary, based on available evidence, the unrealized loss is transferred from other comprehensive income (loss) to the statement of operations. The Company considers various factors in determining the classification, including the length of time and extent to which the fair value has been less than the Company's cost basis, the financial condition and near-term prospects of the issuer or investee, and the Company's ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. There were no charges taken for other-than-temporary declines in fair value of short-term or long-term investments during the three months ended March 31, 2015 and the year ended December 31, 2015. The Company recorded unrealized gains of \$235,994 and \$26,757 during the three months ended March 31, 2016 and 2015, respectively. Realized gains (losses) are included in interest income (expense) in the statement of operations and comprehensive income (loss) on a specific identification basis. The Company did not record any realized gains or losses during the three months ended March 31, 2016 and 2015.

The Company maintains a letter of credit totaling \$112,000 as collateral for the Company's facility lease obligations in Pennsylvania and has recorded this and accumulated interest thereon as restricted cash on its balance sheet.

Fair Value of Financial Instruments

The carrying amount of the Company's financial instruments, which include cash and cash equivalents, marketable securities, restricted cash, accounts payable and accrued expenses approximate their fair values, given their short-term nature. The carrying amount of the Company's loans payable at March 31, 2016 and December 31, 2015 is the nominal value of the loan payable, which is the carrying value, exclusive of debt discount and deferred charges. This approximates fair value because the interest rate is reflective of the rate the Company could obtain on debt with similar terms and conditions. Certain of the Company's common stock warrants are carried at fair value, as disclosed below.

The Company has evaluated the estimated fair value of financial instruments using available market information and management's estimates. The use of different market assumptions and/or estimation methodologies could have a significant effect on the estimated fair value amounts. See Note 3 for additional information.

Table of Contents

Recent Accounting Pronouncements

In March 2016, the FASB issued Accounting Standards Update 2016-09, *Compensation- Stock Compensation* (ASU 2016-09). ASU 2016-09 was issued as part of the FASB Simplification Initiative. This update addresses the income tax effects of stock-based payments and eliminates the windfall pool concept, as all of the tax effects related to stock-based payments will now be recorded at settlement (or expiration) through the income statement. The new guidance also permits entities to make an accounting policy election for the impact of forfeitures on the recognition of expense for stock-based payment awards. Forfeitures can be estimated or recognized when they occur. The standard is effective for annual periods beginning after December 15, 2016 and interim periods within that reporting period. Early adoption is permitted in any interim or annual period, with any adjustment reflected as of the beginning of the fiscal year of adoption. The Company is evaluating the effect this standard will have on its financial statements and related disclosures.

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

In May 2014, the FASB issued 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. Additionally, in March 2016, the FASB issued Accounting Standards Update 2016-08 *Revenue from Contracts with Customers, Principal versus Agent Considerations* (ASU 2016-08). ASU 2016-08 amends the principal versus agent guidance in ASU 2014-09 to clarify how an entity should identify the unit of accounting for the principal versus agent evaluation and how it should apply the control principal to certain types of arrangements. The effective date for both standards is January 1, 2018, with an option that permits companies to adopt the standard as early as the January 1, 2017. Early application prior to the January 1, 2017 is not permitted. The standards permit the use of either the retrospective or cumulative effect transition method. The Company is evaluating the transition method that they will elect. The adoption of these standards are not expected to have a material impact on the Company's financial statements.

In August 2014, the FASB issued Accounting Standards Update 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (ASU 2014-15), which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company's financial statements.

3. Fair Value of Financial Instruments

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

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

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

Table of Contents

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

Cash, Cash Equivalents and Marketable Securities

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 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 months ended March 31, 2016 and 2015. The following table presents the Company's cash and available-for-sale 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 March 31, 2016 and December 31, 2015:

	March 31, 2016					
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash	\$ 6,589,643	\$	\$	\$ 6,589,643	\$ 6,589,643	\$
Level 1(1):						
Money market funds	4,562,623			4,562,623	4,562,623	
Subtotal	4,562,623			4,562,623	4,562,623	
Level 2(2):						
Repurchase agreements	23,300,000			23,300,000	23,300,000	
U.S. government agency securities	128,986,271	49,301	(19,163)	129,016,409		129,016,409
Subtotal	152,286,271	49,301	(19,163)	152,316,409	23,300,000	129,016,409
Total	\$ 163,438,537	\$ 49,301	\$ (19,163)	\$ 163,468,675	\$ 34,452,266	\$ 129,016,409

	December 31, 2015					
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash	\$ 20,672,737	\$	\$	\$ 20,672,737	\$ 20,672,737	\$
Level 1(1):						
Money market funds	4,100,829			4,100,829	4,100,829	
U.S. Treasury securities	12,020,862	92	(1,434)	12,019,520		12,019,520
Subtotal	16,121,691	92	(1,434)	16,120,349	4,100,829	12,019,520
Level 2(2):						
Repurchase agreements	22,000,000			22,000,000	22,000,000	
U.S. government agency securities	114,049,441	269	(204,783)	113,844,927		113,844,927
Subtotal	136,049,441	269	(204,783)	135,844,927	22,000,000	113,844,927
Total	\$ 172,843,869	\$ 361	\$ (206,217)	\$ 172,638,013	\$ 46,773,566	\$ 125,864,447

(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 March 31, 2016, the Company held \$35.3 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.

Table of Contents

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers in or out of Level 3 in the hierarchy during the three months ended March 31, 2016 and the year ended December 31, 2015.

Warrants

At March 31, 2016, 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 \$111,751 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, 2015	\$	153,238
Amounts acquired or issued		
Changes in estimated fair value		(41,487)
Balance as of March 31, 2016	\$	111,751

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 March 31, 2016 and December 31, 2015 to determine the common stock warrant liability:

	March 31, 2016	December 31, 2015
Estimated remaining term	6.1 years	6.3 years
Risk-free interest rate	1.4%	2.0%
Volatility	67.9%	67.4%
Dividend yield	0%	0%
Fair value of underlying instrument*	\$ 8.27	\$ 10.50

* 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 income (loss).

In addition to the outstanding warrant to purchase 20,161 shares of common stock discussed above, the Company also has outstanding warrants to purchase an aggregate of 42,639 shares of the Company's common stock. These warrants qualify for equity classification and have been allocated upon the relative fair value of the base instrument and the warrants, according to the guidance of ASC 470-20-25-2. See Note 6 for additional information.

4. Loans Payable

In September 2014, the Company entered into a loan and security agreement with Oxford Finance LLC and Pacific Western Bank (formerly Square 1 Bank), (together the lenders), pursuant to which the lenders agreed to lend the Company up to \$35.0 million in a three-tranche series of term loans (Term Loans A, B, and C). Upon initially entering into the agreement, the Company borrowed \$2.0 million under Term Loan A. On April 13, 2015, the Company amended the agreement with the lenders to change the draw period for Term Loan B. On December 23, 2015, the Company further amended the agreement with the lenders to, among other things, change the draw period for Term Loan C, modify the interest only period, and modify the maturity date of the loan. In December 2015, the Company borrowed the Term Loan B tranche of \$16.5 million. The Company may now, at its sole discretion, borrow from the lenders an additional \$16.5 million under Term Loan C, at any time on or before December 31, 2016, subject to the satisfaction of specified conditions related to the results of the Company's Phase 2b clinical trial of TRV027.

The proceeds from Term Loan A and Term Loan B, and future proceeds, if any, from 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.

Table of Contents

Borrowings accrue interest at a fixed rate of 6.50% per annum. The Company is required to make payments of interest only on borrowings under the loan agreement on a monthly basis through and including January 1, 2017 (the interest only termination date), after which payments of principal in equal monthly installments and accrued interest will be due until the loan matures on March 1, 2020. Both the interest only termination date and the maturity date may be further modified as follows if the Company meets the conditions to draw on Term Loan C based on the results of the Company's Phase 2b trial of TRV027 by December 31, 2016:

- the interest only termination date will be extended until January 1, 2018; and
- the maturity date will be extended to December 1, 2020 if the Company also has received net cash proceeds of at least \$50.0 million from its existing option and license with Allergan plc (Allergan) or another strategic partnership satisfactory to the lenders.

The Company paid the lenders a facility fee of \$175,000 in connection with the execution of the original agreement and an amendment fee of \$20,000 in connection with the execution of the second amendment to the agreement. Upon the last payment date of the amounts borrowed under the agreement, the Company will be required to pay a final payment fee ranging from 6.1% to 7.0% of the aggregate amounts borrowed. In addition, if the Company repays Term Loan A and Term Loan B prior to 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 December 23, 2016, 2.00% of the total amount prepaid if the prepayment occurs between December 23, 2016 and December 23, 2017, and 1.00% of the total amount prepaid if the prepayment occurs on or after December 24, 2017.

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

The loan and security agreement includes affirmative and restrictive covenants, including: (a) financial reporting requirements; (b) limitations on the incurrence of indebtedness; (c) limitations on liens; (d) limitations on certain merger and acquisition transactions; (e) limitations on dispositions of certain assets; (f) limitations on fundamental corporate changes (including changes in control); (g) limitations on investments; (h) limitations on payments and distributions and (i) other covenants. The agreement also contains certain events of default, including for payment defaults, breaches of covenants, a 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 the agent \$65,000 upon execution of the agreement and \$87,500 upon its draw of Term Loan B; the Company will be obligated to pay up to an additional \$87,500 if it draws on Term Loan C.

In connection with entering into the original agreement, the Company issued to the lenders and the placement agent warrants to purchase an aggregate of 7,678 shares of Trevena common stock. These detachable warrant instruments have qualified for equity classification and have

Edgar Filing: TREVENA INC - Form 10-Q

been allocated upon the relative fair value of the base instrument and the warrants, according to the guidance of ASC 470-20-25-2. These warrants are exercisable immediately and have an exercise price of \$5.8610 per share. The warrants may be exercised on a cashless basis and will terminate on the earlier of September 19, 2024 or the closing of a merger or consolidation transaction in which the Company is not the surviving entity. In connection with the draw of Term Loan B, the Company issued to the lenders and the placement agent additional warrants to purchase an aggregate of 34,961 shares of Trevena common stock. These warrants have substantially the same terms as those described above, have an exercise price of \$10.6190 per share and an expiration date of December 23, 2025. If the Company draws on Term Loan C, it will issue additional warrants to purchase shares of Trevena common stock 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.

As of March 31, 2016, borrowings of \$18.5 million attributable to Term Loans A and B remain outstanding. Interest expense of \$300,625 and \$32,500 was recorded during the three months ended March 31, 2016 and 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 Company incurred lender and third party costs of \$44,058 and \$87,500, respectively, related to the issuance of Term Loan B. The lender costs are classified as a debt discount and the third party costs are classified as debt issuance costs. Per ASU 2015-03, *Interest- Imputation of Interest*, debt discount and debt issuance costs are to be presented as a contra-liability to the debt on the balance sheet. These costs will be amortized to interest expense over the life of loans using the effective interest method. A total of \$33,890 and \$26,783 of debt discount and debt issuance costs was amortized to interest expense during the three months ended March 31, 2016 and 2015, respectively.

Table of Contents

The following table summarizes how the issuance of Term Loans A and B are reflected on the balance sheet at March 31, 2016:

	March 31, 2016
Gross proceeds	\$ 18,500,000
Debt discount	(149,820)
Debt issuance costs	(130,392)
Carrying value	\$ 18,219,788

5. Stockholders Equity

Under its certificate of incorporation, the Company was authorized to issue up to 100,000,000 shares of common stock as of March 31, 2016. The Company also was authorized to issue up to 5,000,000 shares of preferred stock as of March 31, 2016. The Company is required, at all times, to reserve and keep available out of its authorized but unissued shares of common stock sufficient shares to effect the conversion of the shares of any outstanding preferred stock and all outstanding stock options and warrants.

Equity Offerings

In February 2016, the Company issued and sold 1,350,755 shares of common stock through Cowen and Company, LLC, pursuant to an at-the-market sales facility dated December 14, 2015. The shares were sold at a weighted average price per share of \$9.00. The net offering proceeds to the Company were approximately \$11.8 million after deducting related expenses, including commissions.

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 March 31, 2014 (collectively, the 2013 Plan). The 2013 Plan became effective upon the Company s entry into the underwriting agreement related to its initial public offering 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 automatically increases on January 1 of each year beginning in 2015. As of January 1, 2016, the number of shares of common stock that may be issued under the 2013 Plan was automatically increased by 2,032,104 shares, representing 4% of the total number of share of common stock outstanding on December 31, 2015.

Edgar Filing: TREVENA INC - Form 10-Q

Under both the 2008 Plan and the 2013 Plan, the amount, terms of grants and exercisability provisions are determined by the board of directors or its designee. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the board of directors. Vesting generally occurs over a period of not greater than four years.

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

	Three Months Ended March 31,	
	2016	2015
Research and development	\$ 506,050	\$ 227,801
General and administrative	696,676	386,086
Total stock-based compensation	\$ 1,202,726	\$ 613,887

Table of Contents

	Number of Shares	Options Outstanding	
		Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Balance, December 31, 2015	4,630,073	\$ 4.98	7.87
Granted	1,710,500	8.81	
Exercised	(17,600)	2.27	
Forfeitures	(28,375)	6.23	
Balance, March 31, 2016	6,294,598	6.02	8.24
Vested or expected to vest at March 31, 2016	6,003,534	5.91	
Exercisable at March 31, 2016	2,335,787	3.61	

The intrinsic value of the options exercisable as of March 31, 2016 was \$10.9 million, based on the Company's closing stock price of \$8.27 per share and a weighted average exercise price of \$3.61 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 common stock.

The per-share weighted-average grant date fair value of the options granted to employees and directors during the quarter ended March 31, 2016 and 2015 was estimated at \$5.47 and \$4.21 per share, respectively, on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended March 31,	
	2016	2015
Expected term of options (in years)	6.3	6.3
Risk-free interest rate	1.5%	1.7%
Expected volatility	67.8%	68.8%
Dividend yield	0%	0%

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 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

Table of Contents

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 on stock option grants during 2016 and 2015 was 9%, based on the historical forfeiture experience.

At March 31, 2016, there was \$16.2 million of total unrecognized compensation expense related to unvested options that will be recognized over the weighted average remaining period of 3.25 years.

Shares Available for Future Grant

At March 31, 2016, the Company has the following shares available to be granted under the 2013 Plan:

Available at December 31, 2015	959,354
Authorized	2,032,104
Granted	(1,710,500)
Forfeitures/Expirations	28,375
Available at March 31, 2016	1,309,333

Shares Reserved for Future Issuance

At March 31, 2016, the Company has reserved the following shares of common stock for issuance:

Stock options outstanding	6,294,598
Shares available for future grant under 2013 Plan	1,309,333
Employee stock purchase plan	225,806
Warrants outstanding	62,800
	7,892,537

6. Commitments and Contingencies

Licenses

Edgar Filing: TREVENA INC - Form 10-Q

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 conducted, at its expense, a Phase 2b trial of TRV027 in acute heart failure (AHF). In March 2015, Allergan and the Company signed a letter agreement pursuant to which Allergan paid the Company \$10.0 million to fund the expansion of the 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 analysis related to the extended Phase 2b trial is 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.

Table of Contents

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 and cash flows.

7. Revenue

For the three months ended March 31, 2016 and 2015, the Company recognized collaboration revenue of \$1.9 million and \$625,000 related to its March 2015 letter agreement with Allergan. The terms of this agreement contain multiple deliverables which include (i) research and development activities and (ii) testing and analysis related to the 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 arrangements. 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:

Table of Contents

	Three Months Ended March 31,	
	2016	2015
Basic and diluted net loss per common share calculation:		
Net loss	\$ (17,778,979)	\$ (12,929,645)
Accretion of redeemable convertible preferred stock		
Net loss attributable to common stockholders	\$ (17,778,979)	\$ (12,929,645)
Weighted average common shares outstanding	51,350,365	39,251,184
Net loss per share of common stock basic and diluted	\$ (0.35)	\$ (0.33)

The following outstanding securities at March 31, 2016 and 2015 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	March 31,	
	2016	2015
Options outstanding	6,294,598	4,494,427
Warrants	62,800	30,258
Total	6,357,398	4,524,685

9. Comprehensive Income (Loss)

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

Balance, December 31, 2015	\$ (205,856)
Net unrealized gain arising during the period	235,994
Balance, December 31, 2016	\$ 30,138

There were no reclassifications out of accumulated other comprehensive income (loss) during the three months ended March 31, 2016 and 2015. There was no tax effect during the three months ended March 31, 2016 and 2015.

10. Subsequent Events

On May 2, 2016, the company announced the FDA's agreement to certain key elements of the company's Phase 3 program for oliceridine to support a proposed indication for the management of moderate-to-severe acute pain. The FDA also confirmed the need for at least 1,100 patients exposed to oliceridine across the development program for the purposes of evaluating safety and tolerability.

The oliceridine Phase 3 program includes two 375-patient, randomized, double-blind, placebo- and active-controlled, pivotal efficacy trials: the APOLLO-1 study, which will evaluate pain for 48 hours following bunionectomy; and the APOLLO-2 study, which will evaluate pain for 24 hours following abdominoplasty. In each efficacy trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) for the management of their post-operative pain. The primary endpoint for both APOLLO

Edgar Filing: TREVENA INC - Form 10-Q

studies will be a responder analysis comparing active treatment arms to placebo. Secondary endpoints in both APOLLO studies will include comparisons of oliceridine efficacy, safety, and tolerability to morphine. A respiratory safety endpoint will measure prevalence and duration of hypoventilation.

Both the APOLLO-1 and APOLLO-2 trials are expected to start in the second quarter of 2016. The Phase 3 open-label ATHENA-1 safety study commenced in January 2016 and is enrolling patients experiencing pain as a result of either a medical diagnosis or surgery.

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 2015 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC).

Overview

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

- *Oliceridine (TRV130):* We are developing oliceridine as a first line treatment for patients experiencing moderate to severe acute pain where IV administration is preferred. On May 2, 2016, we announced U.S. Food and Drug Administration (FDA) agreement to certain key elements of our Phase 3 program for oliceridine. In addition, we provided details of the planned Phase 3 studies, including two 375-patient, randomized, double-blind, placebo- and active-controlled, pivotal efficacy trials: the APOLLO-1 study, which will evaluate pain for 48 hours following bunionectomy; and the APOLLO-2 study, which will evaluate pain for 24 hours following abdominoplasty. In each efficacy trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) for the management of their post-operative pain. Both the APOLLO-1 and APOLLO-2 trials are expected to start in the second quarter of 2016, and the Phase 3 open-label ATHENA-1 safety study commenced in January 2016. 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. In December 2015 and February 2016, we announced the FDA grant of Fast Track and Breakthrough Therapy designation, respectively, to oliceridine for the management of moderate to severe acute pain.
- *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. Enrollment in this 620-patient study is complete and we expect to release top-line data in the second quarter of 2016. Allergan plc, or Allergan, holds an exclusive option to license TRV027, exercisable at any time through a specified time period after we deliver the data from the BLAST-AHF study to Allergan.
- *TRV250:* We are developing TRV250, a G protein biased ligand targeting the delta receptor, as a compound with a 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 or other opioid related adverse effects 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 FDA in the second half of 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 development and commercialization partner for this asset.

Since our incorporation in late 2007, our operations have included organizing and staffing our company, business planning, raising capital, and discovering and developing our product candidates. We have financed our operations primarily through private placements and public offerings of our equity securities and debt borrowings. As of March 31, 2016, we had an accumulated deficit of \$200.3 million. Our net loss was \$17.8 million and \$12.9 million for the three months ended March 31, 2016 and 2015, 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 Pacific Western Bank (formerly Square 1 Bank), of which we have drawn \$18.5 million as of March 31, 2016. The facility also provides for an additional term loan tranche of \$16.5 million that we may opt to draw if we receive positive data from the Phase 2 clinical trial of TRV027 before December 31, 2016.

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. We will need to obtain substantial additional funding in

Table of Contents

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.

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 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 have conducted, at our expense, a Phase 2b clinical trial of TRV027 in AHF. The Phase 2b clinical trial was conducted pursuant to a mutually agreed upon development plan and under the oversight of a joint development committee, which has an equal number of representatives from us and from Allergan, with operational authority during the option period retained by us, subject to Allergan's right to assume control in certain circumstances if we fail to conduct the development activities adequately.

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, we signed a letter agreement with Allergan pursuant to which Allergan paid us \$10.0 million to fund the expansion of the 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.

Table of Contents

Senior Secured Tranched Term Loan Credit Facility

In September 2014, we entered into a loan and security agreement with Oxford Finance LLC and Pacific Western Bank, or the lenders, pursuant to which they have agreed to lend us up to \$35.0 million in a three-tranche series of term loans (Term Loans A, B, and C). Upon initially entering into the agreement, we borrowed \$2.0 million under Term Loan A. On April 13, 2015, we amended the agreement with the lenders to change the draw period for Term Loan B. On December 23, 2015, we further amended the agreement with the lenders to, among other things, change the draw period for Term Loan C, modify the interest only period, and modify the maturity date of the loan. In December 2015, we borrowed the Term Loan B tranche of \$16.5 million. Subject to the satisfaction of specified conditions related to the results of our Phase 2b clinical trial of TRV027, we may now, at our sole discretion, borrow from the lenders an additional \$16.5 million under Term Loan C, at any time on or before December 31, 2016.

Borrowings accrue interest at a fixed rate of 6.50% per annum. We are required to make payments of interest only on borrowings under the loan agreement on a monthly basis through and including January 1, 2017, which we refer to as the interest only termination date, after which payments of principal in equal monthly installments and accrued interest will be due until the loan matures on March 1, 2020. Both the interest only termination date and the maturity date may be further modified as follows if we meet the conditions to draw on Term Loan C based on the results of our Phase 2b trial of TRV027 by December 31, 2016:

- the interest only termination date will be extended until January 1, 2018, and
- the maturity date will be extended to December 1, 2020 if we also 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 original agreement and an amendment fee of \$20,000 in connection with the execution of the second amendment to 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 Term Loan A and Term Loan B prior to the applicable maturity date, we will pay the Lenders a prepayment fee of 3.0% of the total amount prepaid if the prepayment occurs prior to December 23, 2016, 2.0% of the total amount prepaid if the prepayment occurs between December 23, 2016 and December 23, 2017, and 1.0% of the total amount prepaid if the prepayment occurs on or after December 24, 2017.

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

We used a placement agent in connection with the agreement. We paid the agent \$65,000 upon execution of the agreement and \$87,500 upon our draw of Term Loan B and will be obligated to pay up to an additional \$87,500 if we draw on Term Loan C.

Edgar Filing: TREVENA INC - Form 10-Q

In connection with entering into the original agreement, we issued to the lenders and placement agent warrants to purchase an aggregate of 7,678 shares of our common stock. These warrants are exercisable immediately and have an exercise price of \$5.8610 per share. The warrants may be exercised on a cashless basis and will terminate on the earlier of September 19, 2024 or the closing of a merger or consolidation transaction in which we are not the surviving entity. In connection with draw of Term Loan B, we issued to the lenders and placement agent additional warrants to purchase an aggregate of 34,961 shares of our common stock. These warrants have substantially the same terms as those noted above, have an exercise price of \$10.6190 per share and an expiration date of December 23, 2025. If we draw on Term Loan C, we will issue additional warrants to purchase shares of our common stock 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.

Components of Operating Results

Revenue

To date, we have derived revenue principally from research grants and collaboration arrangements. In March 2015, we signed a letter agreement with Allergan pursuant to which Allergan paid us \$10.0 million to fund the expansion of our 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.

Table of Contents

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.

Change in Fair Value of Warrant Liability

At March 31, 2016, there is an outstanding warrant to purchase up to 20,161 shares of our common stock with a fair value recorded as a liability of \$111,751 as it contains a cash settlement feature upon certain strategic transactions. 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, we develop our 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 our 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 warrant liability is recorded on its own line item on our 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 income (loss).

Other Income

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

Interest expense consists of interest related to our outstanding loan balance.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update 2016-09, *Compensation- Stock Compensation* (ASU 2016-09). ASU 2016-09 was issued as part of the FASB Simplification Initiative. This update addresses the income tax effects of stock-based payments and eliminates the windfall pool concept, as all of the tax effects related to stock-based payments will now be recorded at settlement (or expiration) through the income statement. The new guidance also permits entities to make an accounting policy election for the impact of forfeitures on the recognition of expense for stock-based payment awards. Forfeitures can be estimated or recognized when they occur. The standard is effective for annual periods beginning after December 15, 2016 and interim periods within that reporting period. Early adoption is permitted in any interim or annual period, with any adjustment reflected as of the beginning of the fiscal year of adoption. We are evaluating the effect this standard will have on our financial statements and related disclosures.

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

Table of Contents

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. Additionally, in March 2016, the FASB issued Accounting Standards Update 2016-08 *Revenue from Contracts with Customers, Principal versus Agent Considerations* (ASU 2016-08). ASU 2016-08 amends the principal versus agent guidance in ASU 2014-09 to clarify how an entity should identify the unit of accounting for the principal versus agent evaluation and how it should apply the control principal to certain types of arrangements. The effective date for both standards is January 1, 2018, with an option that permits companies to adopt the standard as early as the January 1, 2017. Early application prior to the January 1, 2017 is not permitted. The standards permit the use of either the retrospective or cumulative effect transition method. We are evaluating the transition method we will elect. The adoption of these standards are not expected to have a material impact on our financial statements.

In August 2014, the FASB issued Accounting Standards Update 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (ASU 2014-15), which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance 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 to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

Results of Operations*Comparison of the Three Months Ended March 31, 2016 and 2015*

	Three Months Ended March 31,			
	2016		2015	Change
Revenue:				
Collaboration revenue	\$ 1,875,000		\$ 625,000	\$ 1,250,000
Total revenue	1,875,000		625,000	1,250,000
Operating expenses:				
General and administrative	3,917,750		3,089,622	828,128
Research and development	15,753,087		10,598,993	5,154,094
Total operating expenses	19,670,837		13,688,615	5,982,222
Loss from operations	(17,795,837)		(13,063,615)	(4,732,222)
Other income (expense):				
Change in fair value of warrant liability	41,487		(8,413)	49,900
Miscellaneous income	221,402		173,535	47,867

Edgar Filing: TREVENA INC - Form 10-Q

Interest income	193,134	39,469	(153,665)
Interest expense	(439,165)	(70,621)	(368,544)
Total other income	16,858	133,970	(117,112)
Net loss attributable to common stockholders	\$ (17,778,979)	\$ (12,929,645)	\$ (4,849,334)

Revenue

Collaboration revenue increased \$1.3 million for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015 due to our entry into a letter agreement with Actavis plc, a predecessor to Allergan, on March 5, 2015. Under this agreement, Actavis 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 is being recorded on a straight-line basis through the expected term of the trial.

Table of Contents*General and administrative expense*

General and administrative expenses increased by \$0.8 million, or 27%, for the three months ended March 31, 2016 compared to the same period in 2015 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 increased by \$5.2 million, or 49%, from \$10.6 million for the three months ended March 31, 2015 to \$15.8 million for the three months ended March 31, 2016. The following table summarizes our research and development expenses:

	Three Months Ended March 31,	
	2016	2015
Personnel related costs	\$ 3,046,058	\$ 2,223,587
Oliceridine (TRV130)	7,045,321	5,134,667
TRV027	3,452,584	2,121,196
Other research and development	2,209,124	1,119,543
	\$ 15,753,087	\$ 10,598,993

The increase in research and development expenses was primarily driven by (i) increased headcount and associated salary, benefit, bonus and stock based compensation expense, (ii) increased expenditures during 2016 on oliceridine including expenses associated with initiating our Phase 3 program partially offset by a decrease in expenses associated with the completion of the phase 2b abdominoplasty clinical trial, (iii) increased expenditures on the phase 2b clinical trial of TRV027 (BLAST-AHF) for the treatment of AHF due to increased enrollment in 2016 compared to 2015 and (iv) higher expenditures for discovery research and TRV250 preclinical development during 2016 partially offset by a decrease in expenditures on our TRV734 program.

Liquidity and Capital Resources

We incurred net losses of \$17.8 million and \$12.9 million for the three months ended March 31, 2016 and 2015, respectively. Net cash used in operating activities was \$20.6 million and \$6.0 million during the three months ended March 31, 2016 and 2015, respectively. At March 31, 2016, we had an accumulated deficit of \$200.3 million, working capital of \$156.4 million, cash and cash equivalents of \$34.5 million and marketable securities of \$129.0 million. In February 2014, we completed our initial public offering, in December 2014 and September 2015 we completed underwritten follow-on offerings of common stock, and in February 2016, July 2015 and May 2015 we sold shares of common stock through Cowen and Company, LLC, or Cowen, pursuant to at-the-market, or ATM, sales facilities (see Operating and Capital Expenditure Requirements below).

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,	
	2016	2015
Net cash (used in) provided by:		
Operating activities	\$ (20,647,238)	\$ (6,034,638)
Investing activities	(3,508,936)	(1,213,809)
Financing activities	11,834,874	178,783
Net decrease in cash and cash equivalents	\$ (12,321,300)	\$ (7,069,664)

Net cash used in operating activities

Net cash used in operating activities was \$20.6 million for the three months ended March 31, 2016, consisting primarily of a net loss of \$17.8 million partially offset by noncash adjustments of \$1.8 million and changes in operating assets and liabilities of \$4.6 million. Changes in operating assets and liabilities were primarily driven by a decrease of deferred revenue of \$1.9 million associated with the payment received from Activis in March 2015 partially offset by a decrease in prepaid expenses and other assets of \$0.6 million and a decrease in accounts payable and accrued expenses of \$2.2 million. These changes result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Table of Contents

Net cash used in operating activities was \$6.0 million for the three months ended March 31, 2015, consisting primarily of a net loss of \$12.9 million partially offset by noncash adjustments of \$0.7 million and changes in operating assets and liabilities of \$6.2 million. Changes in operating assets and liabilities were primarily driven by an increase of deferred revenue of \$9.4 million associated with the payment received from Actavis in March 2015 partially offset by a decrease in prepaid expenses and other assets of \$0.8 million and a decrease in accounts payable and accrued expenses of \$2.4 million.

Net cash used in investing activities

Net cash used in investing activities for the three months ended March 31, 2016 and 2015 was \$3.5 million and \$1.2 million, respectively, and was due primarily to the investment of proceeds from our sales of common stock 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 \$11.8 million for the three months ended March 31, 2016, which was due to net proceeds of \$11.8 million from the sale of common stock through Cowen, pursuant to an ATM sales facility and proceeds from exercises of common stock options.

Net cash provided by financing activities was \$178,783 for the three months ended March 31, 2015, which was primarily due to 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 continue to fund our Phase 3 clinical program for oliceridine (TRV130) and prepare for commercialization of this product candidate, 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.

We believe that our cash and cash equivalents and marketable securities as of March 31, 2016, together with interest thereon, will be sufficient to fund our operating expenses and capital expenditure requirements into 2018. 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 December 2015, we filed a \$250 million shelf registration statement that includes a \$75 million ATM sales facility with Cowen acting as our sales agent. Approximately \$62.8 million remains available under the ATM sales facility as of March 31, 2016. We may offer and sell shares of our common stock under the existing registration

Edgar Filing: TREVENA INC - Form 10-Q

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, on or before December 31, 2016, we may have the option to draw \$16.5 million under our existing loan and security agreement with Oxford Finance LLC and Pacific Western Bank, subject to the satisfaction of specified conditions related to the results of our Phase 2b clinical trial of TRV027.

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

Table of Contents

- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the costs, timing and outcome of regulatory review of our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims, both in the United States and in territories outside the United States.

Please see **Risk Factors** section of this Quarterly Report and our most recent Annual Report on Form 10-K as filed with the SEC and which is incorporated herein by reference, for additional risks associated with our substantial capital requirements.

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 which is incorporated herein by reference, for full detail. We did not make any significant changes to our critical accounting policies during the quarter ended March 31, 2016.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

We had cash and cash equivalents of \$34.5 million and marketable securities of \$129.0 million at March 31, 2016, consisting primarily of funds in cash, money market funds, U.S. Treasury and U.S. government agency securities. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe

Table of Contents

an immediate 10.0% increase or decrease in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

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 March 31, 2016, 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.

PART II

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

There have been no material changes to our risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, with the exception of the following risk factor:

If Allergan exercises its option to license TRV027, that relationship will become even more important to our business, and any future relationships or collaborations we may enter into also may be important to us. If we are unable to maintain our relationship with Allergan or any of these collaborations, or if our relationship with Allergan or these collaborators is not successful, our business could be adversely affected.

We have limited capabilities for product development, sales, marketing and distribution. We have an option agreement and a license agreement with Allergan that provide Allergan with an option to license TRV027. If Allergan exercises this option, it will be responsible for subsequent development, regulatory approval and commercialization of TRV027, and we will be eligible to receive milestone payments and royalties on product sales. This relationship, any future collaboration with Allergan, and any future collaborations we might enter into with another third party, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;

Table of Contents

- collaborators may elect not to continue or renew development or commercialization programs or may not pursue commercialization of any product candidates that achieve regulatory approval based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to limit or eliminate efforts and resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated at the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our potential collaboration with Allergan, or any other collaborations we might enter into in the future, do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product platform and product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform. The risks relating to our product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of our therapeutic program collaborators.

If Allergan exercises its option to license TRV027 from us, the license agreement will contain a restriction on our engaging in activities relating to certain product candidates that may compete with TRV027 for a specified period of time. This restriction may have the effect of preventing us from undertaking development and other efforts for TRV027 or another product candidate that we would otherwise prefer to pursue. Additionally, subject to its contractual obligations to us, if Allergan or a future collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

For our product candidates other than TRV027, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of these candidates. We face significant competition in

Table of Contents

seeking appropriate collaborators. Our ability to reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Edgar Filing: TREVENA INC - Form 10-Q

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 three months ended March 31, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets as of March 31, 2016 and December 31, 2015, (ii) Statements of Operations and Comprehensive Income (Loss) for the three months ended March 31, 2016 and 2015, (iii) Statement of Stockholders' Equity as of March 31, 2016, (iv) Statements of Cash Flows for the three months ended March 31, 2016 and 2015 and (v) Notes to Unaudited Financial Statements, tagged as blocks of text.

* Filed herewith.

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: May 5, 2016

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 March 31, 2016, formatted in XBRL(eXtensible Business Reporting Language): (i) Balance Sheets as of March 31, 2016 and December 31, 2015, (ii) Statements of Operations and Comprehensive Income (Loss) for the three months ended March 31, 2016 and 2015, (iii) Statement of Stockholders Equity as of March 31, 2016, (iv) Statements of Cash Flows for the three months ended March 31, 2016 and 2015 and (v) Notes to Unaudited Financial Statements, tagged as blocks of text.