TREVENA INC
Form 10-Q
August 04, 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 June 30, 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	26-1469215
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

1018 West 8th Avenue, Suite A	
King of Prussia, PA	19406
(Address of Principal Executive Offices)	(Zip Code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer	Accelerated filer
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 August 1, 2016: 52,178,174

Table of Contents

TABLE OF CONTENTS

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," "pla "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- our plans to develop and potentially commercialize our product candidates;
- our ability to fund future operating expenses and capital expenditures with our current cash resources;
- our planned clinical trials and preclinical studies for our product candidates;
- the timing and likelihood of obtaining and maintaining regulatory approvals for our product candidates;
- 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

	June 30, 2016 (unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 36,802,778	$ 46,773,566
Marketable securities	107,707,828	125,864,447
Prepaid expenses and other current assets	3,129,866	1,892,217
Total current assets	147,640,472	174,530,230
Property and equipment, net	807,353	696,280
Restricted cash	112,620	112,620
Intangible asset, net	13,906	14,844
Total assets	$ 148,574,351	$ 175,353,974
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,925,372	$ 6,749,625
Accrued expenses and other current liabilities	3,785,223	3,029,782
Deferred revenue	—	3,750,000
Deferred rent	48,086	43,907
Total current liabilities	8,758,681	13,573,314
Loans payable, net	18,249,810	18,185,898
Capital leases, net of current portion	13,176	7,942
Deferred rent, net of current portion	214,679	238,917
Warrant liability	83,517	153,238
Other long term liabilities	270,532	63,200
Total liabilities	27,590,395	32,222,509
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock—$0.001 par value; 100,000,000 shares authorized, 52,177,674 and 50,802,603 shares issued and outstanding at June 30, 2016 and	52,178	50,802

December 31, 2015, respectively		
Preferred stock—$0.001 par value; 5,000,000 shares authorized, none issued or outstanding at June 30, 2016 and December 31, 2015, respectively	—	—
Additional paid-in capital	340,349,923	325,784,484
Accumulated deficit	(219,493,262)	(182,497,965)
Accumulated other comprehensive income (loss)	75,117	(205,856)
Total stockholders' equity	120,983,956	143,131,465
Total liabilities and stockholders' equity	$ 148,574,351	$ 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue:				
Collaboration revenue	$ 1,875,000	$ 1,875,000	$ 3,750,000	$ 2,500,000
Total revenue	1,875,000	1,875,000	3,750,000	2,500,000
Operating expenses:				
General and administrative	3,696,682	3,107,263	7,614,432	6,196,885
Research and development	17,203,345	10,275,470	32,956,432	20,874,463
Total operating expenses	20,900,027	13,382,733	40,570,864	27,071,348
Loss from operations	(19,025,027)	(11,507,733)	(36,820,864)	(24,571,348)
Other income (expense):				
Change in fair value of warrant liability	28,234	5,348	69,721	(3,065)
Gain on asset disposal	—	2,656	—	2,656
Miscellaneous income	—	—	221,699	173,535
Interest income	214,376	53,219	407,213	92,688
Interest expense	(433,901)	(72,341)	(873,066)	(142,962)
Total other (expense) income	(191,291)	(11,118)	(174,433)	122,852
Net loss attributable to common stockholders	$ (19,216,318)	$ (11,518,851)	$ (36,995,297)	$ (24,448,496)
Other comprehensive income, net:				
Change in unrealized gains on marketable securities	44,979	2,127	280,973	28,884
Other comprehensive income	44,979	2,127	280,973	28,884
Comprehensive loss	$ (19,171,339)	$ (11,516,724)	$ (36,714,324)	$ (24,419,612)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.37)	$ (0.28)	$ (0.71)	$ (0.61)
Weighted average common shares outstanding, basic and diluted	52,174,569	40,809,931	51,762,467	40,034,864

See accompanying notes to financial statements.

2

Table of Contents

TREVENA, INC.

Statement of Stockholders' Equity (Unaudited)

For the period from January 1, 2016 to June 30, 2016

	Stockholders' Equity Common Stock					
	Number of Shares	$0.001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance, January 1, 2016	50,802,603	$ 50,802	$ 325,784,484	$ (182,497,965)	$ (205,856)	$ 143,131,465
Stock-based compensation expense	—	—	2,713,109	—	—	2,713,109
Exercise of stock options	23,618	25	61,283	—	—	61,308
Net exercise of common stock warrant	698	—	—	—	—	—
Issuance of common stock, net of issuance costs	1,350,755	1,351	11,791,047	—	—	11,792,398
Unrealized gain on marketable securities	—	—	—	—	280,973	280,973
Net loss	—	—	—	(36,995,297)	—	(36,995,297)
Balance, June 30, 2016	52,177,674	$ 52,178	$ 340,349,923	$ (219,493,262)	$ 75,117	$ 120,983,956

See accompanying notes to financial statements.

3

Table of Contents

TREVENA, INC.

Statements of Cash Flows (Unaudited)

	Six Months Ended June 30,	
	2016	2015
Operating activities:		
Net loss	$ (36,995,297)	$ (24,448,496)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	118,547	104,499
Stock-based compensation	2,713,109	1,458,107
Noncash interest expense on loans	271,243	77,549
Revaluation of warrant liability	(69,721)	3,065
Amortization of bond premiums on marketable securities	803,915	548,784
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,237,649)	(214,010)
Accounts payable and accrued expenses	(1,090,571)	(1,307,695)
Deferred revenue	(3,750,000)	7,500,000
Net cash used in operating activities	(39,236,424)	(16,278,197)
Investing activities:		
Purchases of property and equipment	(219,737)	(160,550)
Maturities of marketable securities	55,014,000	35,230,000
Purchases of marketable securities	(37,380,322)	(27,767,435)
Net cash provided by investing activities	17,413,941	7,302,015
Financing activities:		
Proceeds from exercise of common stock options	61,308	196,717
Proceeds from issuance of common stock, net	11,792,398	16,240,932
Capital lease payments	(2,011)	(1,260)
Net cash provided by financing activities	11,851,695	16,436,389
Net (decrease) increase in cash and cash equivalents	(9,970,788)	7,460,207
Cash and cash equivalents—beginning of period	46,773,566	36,205,559
Cash and cash equivalents—end of period	$ 36,802,778	$ 43,665,766
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 601,823	$ 65,413
Capital lease additions	$ 8,944	$ —

See accompanying notes to financial statements.

4

Table of Contents

TREVENA, INC.

Notes to Unaudited Financial Statements

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 June 30, 2016, the Company had an accumulated deficit of $219.5 million. The Company's net loss was $37.0 million and $24.4 million for the six months ended June 30, 2016 and 2015, respectively. The Company expects its cash and cash equivalents of $36.8 million and marketable securities of $107.7 million as of June 30, 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

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 balance sheet as of June 30, 2016, its results of operations and its comprehensive income (loss) for the three and six months ended June 30, 2016 and 2015, its statement of stockholders' equity for the period from January 1, 2016 to June 30, 2016 and its cash flows for the six months ended June 30, 2016 and 2015. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 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

Table of Contents

must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. In preparing these financial statements, management used significant estimates in the following areas, among others: stock-based compensation expense, the determination of the fair value of stock-based awards, the fair value of liability-classified 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 June 30, 2016 and December 31, 2015, the Company had $107.7 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 the Company's 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 and six months ended June 30, 2016. The Company recorded unrealized gains of $44,979 and $2,127 during the three months ended June 30, 2016 and 2015, respectively, and $280,973 and $28,884 during the six months ended June 30, 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 six months ended June 30, 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.

Table of Contents

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 June 30, 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.

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 is 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

Table of Contents

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.

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 and six months ended June 30, 2016 and 2015. The following table presents the Company’s cash and available-for-sale securities’ adjusted cost, gross unrealized gains,

Table of Contents

gross unrealized losses and fair value by significant investment category recorded as cash and cash equivalents or marketable securities as of June 30, 2016 and December 31, 2015:

	June 30, 2016					
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash	$ 11,881,989	$ —	$ —	$ 11,881,989	$ 11,881,989	$ —
Level 1 (1):						
Money market funds	14,920,789	—	—	14,920,789	14,920,789	—
Level 2 (2):						
Repurchase agreements	10,000,000	—	—	10,000,000	10,000,000	—
U.S. government agency securities	107,632,711	78,553	(3,436)	107,707,828	—	107,707,828
Subtotal	117,632,711	78,553	(3,436)	117,707,828	10,000,000	107,707,828
Total	$ 144,435,489	$ 78,553	$ (3,436)	$ 144,510,606	$ 36,802,778	$ 107,707,828

	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	114,049,441	269	(204,783)	113,844,927	—	113,844,927

securities						
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 June 30, 2016, the Company held $18.1 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.

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 and six months ended June 30, 2016.

Table of Contents

Warrants

At June 30, 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 $83,517 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	(69,721)
Balance as of June 30, 2016	$ 83,517

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 June 30, 2016 and December 31, 2015 to determine the common stock warrant liability:

	June 30, 2016		December 31, 2015	
Estimated remaining term	5.8	years	6.3	years
Risk-free interest rate	1.1	%	2.0	%
Volatility	76.2	%	67.4	%
Dividend yield	0	%	0	%
Fair value of underlying instrument*	$ 6.30		$ 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 40,689 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's ability to draw an additional $16.5 million under Term Loan C was subject to the satisfaction of one or more specified triggers related to the results of the Company's Phase 2b clinical trial of TRV027, which were announced in May 2016. While certain of the triggers to draw on Term Loan C

Table of Contents

were not attained as of June 30, 2016, the Company is continuing to assess the remaining triggers to determine its eligibility to draw on Term Loan C.

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

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, after which payments of principal in equal monthly installments and accrued interest will be due until the loan matures on March 1, 2020. If, based on the Company's ongoing evaluation, it is eligible to draw on Term Loan C, monthly interest only payments will be extended to January 1, 2018 and the loan maturity date will be extended to December 1, 2020.

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 of 6.1% 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 3.0% 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.

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.

In connection with entering into the original agreement, the Company issued to the lenders and the placement agent warrants to purchase an aggregate of 7,678 shares of the Company's common stock, and 5,728 remain outstanding as of June 30, 2016. These detachable warrant instruments have qualified for equity classification and have been allocated upon the relative fair value of the base instrument and the warrants, according to the guidance of ASC 470-20-25-2. These warrants are exercisable immediately and have an exercise price of $5.8610 per share. The warrants may be exercised on a cashless basis and will terminate on the earlier of September 19, 2024 or the closing of a merger or consolidation transaction in which the Company is not the surviving entity. In connection with the draw of Term Loan B, the Company issued to the lenders and the placement agent additional warrants to purchase an aggregate of 34,961 shares of the Company's common stock. These warrants have substantially the same terms as those described above, and have an exercise price of $10.6190 per share and an expiration date of December 23, 2025.

As of June 30, 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 June 30, 2016 and 2015, respectively, and $601,250 and $65,000 was recorded during the six months ended June 30, 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

Table of Contents

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 the loans using the effective interest method. A total of $30,022 and $29,000 of debt discount and debt issuance cost was amortized to interest expense during the three months ended June 30, 2016 and 2015 respectively, and $63,912 and $58,000 of debt discount and debt issuance costs was amortized to interest expense during the six months ended June 30, 2016 and 2015, respectively.

The following table summarizes how the issuance of Term Loans A and B are reflected on the balance sheet at June 30, 2016:

	June 30, 2016
Gross proceeds	$ 18,500,000
Debt discount	(133,768)
Debt issuance costs	(116,422)
Carrying value	$ 18,249,810

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 June 30, 2016. The Company also was authorized to issue up to 5,000,000 shares of preferred stock as of June 30, 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 shares of common stock outstanding on December 31, 2015.

Table of Contents

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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development	$ 622,746	$ 350,022	$ 1,128,796	$ 577,823
General and administrative	887,637	494,198	1,584,312	880,284
Total stock-based compensation	$ 1,510,383	$ 844,220	$ 2,713,108	$ 1,458,107

	Options Outstanding		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Balance, December 31, 2015	4,630,073	$ 4.98	7.87
Granted	1,902,500	8.61	
Exercised	(23,618)	2.60	
Forfeited/Cancelled	(28,375)	6.22	
Balance, June 30, 2016	6,480,580	$ 6.05	8.05
Vested or expected to vest at June 30, 2016	6,209,938	$ 5.95	7.99
Exercisable at June 30, 2016	2,579,905	$ 3.81	6.66

The intrinsic value of the options exercisable as of June 30, 2016 was $7.3 million, based on the Company's closing stock price of $6.30 per share and a weighted average exercise price of $3.81 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 June 30, 2016 and 2015 was estimated at $5.34 and $4.26 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Six Months Ended June 30,	
	2016	2015
Expected term of options (in years)	6.2	6.2
Risk-free interest rate	1.47 %	1.68 %
Expected volatility	67.9 %	68.9 %
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.

Table of Contents

- 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' stock were selected based on their enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected term of the associated award. A decrease in the selected volatility would have decreased the fair value of the underlying instrument.

- Expected annual dividend yield: The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in the continued growth of the business. Accordingly, the Company assumed an expected dividend yield of 0%.

- 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 June 30, 2016, there was $15.7 million of total unrecognized compensation expense related to unvested options that will be recognized over the weighted average remaining period of 3.01 years.

Shares Available for Future Grant

At June 30, 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	(1,902,500)
Forfeited/Cancelled	28,375
Available at June 30, 2016	1,117,333

Shares Reserved for Future Issuance

At June 30, 2016, the Company has reserved the following shares of common stock for issuance:

Stock options outstanding	6,480,580
Shares available for future grant under 2013 Plan	1,117,333
Employee stock purchase plan	225,806
Warrants outstanding	60,850
	7,884,569

6. Commitments and Contingencies

Licenses

On May 3, 2013, the Company entered into an option agreement and a license agreement with Allergan plc (formerly Actavis plc and Forest Laboratories Holdings Limited) (“Allergan”), under which the Company granted to Allergan an exclusive option to license its product candidate, TRV027.

Table of Contents

Under the option agreement, the Company conducted, at its expense, a Phase 2b trial of TRV027 in acute heart failure. 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. Collaboration revenue has been recognized on a straight-line basis over the study period and has been fully recognized as of June 30, 2016. The March 2015 letter agreement does not otherwise amend the terms of the May 2013 option agreement.

In August 2016, Allergan notified the Company of its decision to not exercise its option. As such, the Company has retained all rights to TRV027.

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 each of the three months ended June 30, 2016 and 2015, the Company recognized collaboration revenue of $1.9 million, and for the six months ended June 30, 2016 and 2015, the Company recognized collaboration revenue of $3.8 million and $2.5 million, respectively, 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, 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.

Table of Contents

8. Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Basic and diluted net loss per common share calculation:				
Net loss	$ (19,216,318)	$ (11,518,851)	$ (36,995,297)	$ (24,448,496)
Net loss attributable to common stockholders	$ (19,216,318)	$ (11,518,851)	$ (36,995,297)	$ (24,448,496)
Weighted average common shares outstanding	52,174,569	40,809,931	51,762,467	40,034,864
Net loss per share of common stock - basic and diluted	$ (0.37)	$ (0.28)	$ (0.71)	$ (0.61)

The following outstanding securities at June 30, 2016 and 2015 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	June 30,	
	2016	2015
Options outstanding	6,480,580	4,662,860
Warrants	60,850	27,839
Total	6,541,430	4,690,699

9. Other Comprehensive Income

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 gains on marketable securities	280,973
Balance, June 30, 2016	$ 75,117

There were no reclassifications out of accumulated other comprehensive income during the three or six months ended June 30, 2016 and 2015. There was no tax effect during the three or six months ended June 30, 2016 and 2015.

10. Subsequent Events

In August 2016, Allergan notified the Company of its decision to not exercise its option to exclusively license TRV027. As such, the Company has retained all rights to TRV027.

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 unaudited financial statement and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2015, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 9, 2016. Unless the context otherwise requires, we use the terms "Trevena," "company," "we," "us" and "our" to refer to Trevena, Inc.

Overview

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

· Oliceridine (TRV130): We are developing oliceridine, a μ-receptor G protein pathway selective modulator (μ-GPS), as a first line treatment for patients experiencing moderate to severe acute pain where intravenous, or IV administration is preferred. On May 2, 2016, we announced U.S. Food and Drug Administration, or FDA, agreement to certain key elements of our Phase 3 program for oliceridine. The program includes two 375-patient, randomized, double-blind, placebo- and active-controlled, pivotal efficacy trials: the APOLLO-1 study, which is evaluating the analgesic efficacy of oliceridine over 48 hours following bunionectomy; and the APOLLO-2 study, which is evaluating the analgesic efficacy of oliceridine over 24 hours following abdominoplasty. In each efficacy trial, patients are randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia, or PCA, device for the management of their post-operative pain. Both the APOLLO-1 and APOLLO-2 trials commenced enrollment 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.

· TRV250: We are developing TRV250, a G protein biased ligand targeting the -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 we believe it will not 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 product candidates, we identified and have completed the Phase 1 program for TRV734, an orally administered new chemical entity expected to be used for first-line treatment of moderate to severe acute and

chronic pain. We intend to continue to focus our efforts for TRV734 on securing a development and commercialization partner for this asset. We had also been developing TRV027 for the treatment of acute heart failure, or AHF. In May 2016, we announced that TRV027 failed to meet either the primary or secondary endpoints of the Phase 2b (BLAST-AHF) clinical trial. We are continuing to evaluate the data from this clinical trial. In August 2016, Allergan plc (formerly Actavis plc and Forest Laboratories Holdings Limited), or Allergan, notified us of its decision to not exercise its exclusive option to license TRV027.

Since our incorporation in late 2007, our operations have included organizing and staffing our company, business planning, raising capital, and discovering and developing our product candidates. We have financed our operations primarily through private placements and public offerings of our equity securities and debt borrowings. As of June 30, 2016, we had an accumulated deficit of $219.5 million. Our net loss was $37.0 million and $24.4 million for the six months ended June 30, 2016 and 2015, respectively. Our ability to become and remain profitable depends on our

Table of Contents

ability to generate revenue or sales. We do not expect to generate significant revenue or sales unless and until we or a collaborator obtain marketing approval for and commercialize oliceridine, TRV250 or TRV734.

In September 2014, we announced we had entered into a $35.0 million senior secured tranched 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 June 30, 2016. We are assessing our eligibility to draw the $16.5 million that remains under the credit facility based on our potential satisfaction of specific triggers related to the results of our Phase 2b clinical trial of TRV027, which were announced in May 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 connection with our continuing operations. We will seek to fund our operations through the sale of equity, debt financings or other sources, including potential additional collaborations. However, we may be unable to raise additional funds or enter into such other agreements when needed on favorable terms, or at all. If we fail to raise capital or enter into such other arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue our research and development programs and/or any future commercialization efforts.

Option and License Agreements with Allergan plc

On May 3, 2013, we entered into an option agreement and a license agreement with Allergan, under which we granted to Allergan an exclusive option to license TRV027. 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.

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 was recorded on a straight-line basis through the expected term of the trial and has been fully recognized as of June 30, 2016. The March 2015 letter agreement does not otherwise amend the terms of the May 2013 option agreement.

In August 2016, Allergan notified us of its decision to not exercise its option. As such, we have retained all rights to TRV027.

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. Our ability to draw an additional $16.5 million under Term Loan C was subject to the satisfaction of one of more specified triggers related to the results of our Phase 2b clinical trial of TRV027. While certain of the triggers to draw on Term Loan C were not attained as of June 30, 2016, we are continuing to assess the remaining triggers to determine our eligibility to draw on Term Loan C.

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, after which payments of principal in equal monthly installments and accrued interest will be due until the loan matures on March 1, 2020. If we are eligible to draw on Term Loan C, which we are continuing to evaluate, monthly interest only payments will be extended to January 1, 2018 and the loan maturity date will be extended to December 1, 2020.

Table of Contents

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 of 6.1% 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.

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, and 5,728 remain outstanding as of June 30, 2016. 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, and have an exercise price of $10.6190 per share and an expiration date of December 23, 2025.

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 was be recognized on a straight-line basis through the completion date of the trial and has been fully recognized as of June 30, 2016.

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

Table of Contents

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 June 30, 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 $83,517 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, or 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), or 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.

In May 2014, the FASB issued Accounting Standards Update 2014-09, Revenue from Contracts with Customers, or 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, or 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

Table of Contents

evaluating the transition method we will elect. The adoption of these standards is 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, or 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 Jumpstart Our Business Startups Act of 2012, or the JOBS Act contains provisions that, among other things, reduce reporting requirements for an "emerging growth company." As an emerging growth company, we have elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2016 and 2015

	Three Months Ended June 30,			Six Months Ended June 30,		
	2016	2015	Change	2016	2015	Change
Revenue:						
Collaboration revenue	$ 1,875,000	$ 1,875,000	$ —	$ 3,750,000	$ 2,500,000	$ 1,250,000
Total revenue	1,875,000	1,875,000	—	3,750,000	2,500,000	1,250,000
Operating expenses:						
General and administrative	3,696,682	3,107,263	589,419	7,614,432	6,196,885	1,417,547
Research and development	17,203,345	10,275,470	6,927,875	32,956,432	20,874,463	12,081,969
	20,900,027	13,382,733	7,517,294	40,570,864	27,071,348	13,499,516

Total operating expenses						
Loss from operations	(19,025,027)	(11,507,733)	(7,517,294)	(36,820,864)	(24,571,348)	(12,249,516)
Other income (expense):						
Change in fair value of warrant liability	28,234	5,348	22,886	69,721	(3,065)	72,786
Gain on asset disposal	—	2,656	(2,656)	—	2,656	(2,656)
Miscellaneous income	—	—	—	221,699	173,535	48,164
Interest income	214,376	53,219	161,157	407,213	92,688	314,525
Interest expense	(433,901)	(72,341)	(361,560)	(873,066)	(142,962)	(730,104)
Total other (expense) income	(191,291)	(11,118)	(180,173)	(174,433)	122,852	(297,285)
Net loss attributable to common stockholders	$ (19,216,318)	$ (11,518,851)	$ (7,697,467)	$ (36,995,297)	$ (24,448,496)	$ (12,546,801)

Revenue

Collaboration revenue was the same amount for the three months ended June 30, 2016 and 2015 and increased $1.3 million for the six months ended June 30, 2016 as compared to the six months ended June 30, 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 was recorded on a straight-line basis and has been fully recognized as of June 30, 2016.

General and administrative expense

General and administrative expenses increased by $0.6 million, or 19%, and $1.4 million, or 23%, for the three and six months ended June 30, 2016, respectively, as compared to the same periods in 2015 primarily as a result of increased headcount and associated salary, bonus and stock compensation expenses, and market research expenditures.

21

Table of Contents

Research and development expense

Research and development expenses increased by $6.9 million, or 67%, and $12.1 million, or 58%, for the three and six months ended June 30, 2016, respectively, as compared to the same periods in 2015. The following table summarizes our research and development expenses:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Personnel-related costs	$ 3,112,343	$ 2,244,087	$ 6,158,401	$ 4,467,674
Oliceridine (TRV130)	10,085,063	4,735,144	17,130,384	9,869,811
TRV027	1,894,964	1,906,015	5,347,548	4,027,211
Other research and development	2,110,975	1,390,224	4,320,099	2,509,767
	$ 17,203,345	$ 10,275,470	$ 32,956,432	$ 20,874,463

The increase in research and development expenses during the three months ended June 30, 2016 was primarily driven by (i) increased expenditures during 2016 on the development of 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 and certain other clinical work and (ii) increased headcount and associated salary, benefits and stock based compensation expense.

The increase in research and development expenses during the six months ended June 30, 2016 was primarily driven by (i) 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 and certain other clinical work as well as expenses associated with oliceridine medical affairs activities, (ii) the initiation of TRV250 IND-enabling studies during 2016, (iii) increased headcount and associated salary, benefits and stock based compensation expense and (iv) increased expenditures on the Phase 2b clinical trial of TRV027 (BLAST-AHF) due to increased enrollment in 2016 as compared to 2015.

Liquidity and Capital Resources

We incurred net losses of $37.0 million and $24.4 million for the six months ended June 30, 2016 and 2015, respectively. Net cash used in operating activities was $39.2 million and $16.3 million during the six months ended June 30, 2016 and 2015, respectively. At June 30, 2016, we had an accumulated deficit of $219.5 million, working capital of $138.9 million, cash and cash equivalents of $36.8 million and marketable securities of $107.7 million. In September 2015 we completed an underwritten follow-on offering of our 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

an 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 six months ended June 30, 2016 and 2015:

	Six Months Ended June 30,	
	2016	2015
Net cash (used in) provided by:		
Operating activities	$ (39,236,424)	$ (16,278,197)
Investing activities	17,413,941	7,302,015
Financing activities	11,851,695	16,436,389
Net (decrease) increase in cash and cash equivalents	$ (9,970,788)	$ 7,460,207

Table of Contents

Net cash used in operating activities

Net cash used in operating activities was $39.2 million for the six months ended June 30, 2016 and consisted primarily of a net loss of $37.0 million and net cash outflows from changes in operating assets and liabilities of $6.1 million, which consisted of a decrease in deferred revenue of $3.8 million, an increase in prepaid expense and other assets of $1.2 million and a decrease in accounts payable, accrued expenses and other liabilities of $1.1 million. These cash outflows were partially offset by non-cash expense for stock compensation of $2.7 million and other non-cash adjustments in our net loss totaling $1.0 million.

Net cash used in operating activities was $16.3 million for the six months ended June 30, 2015, consisting primarily of a net loss of $24.4 million partially offset by noncash adjustments of $2.2 million and changes in operating assets and liabilities of $6.0 million. Changes in operating assets and liabilities were primarily driven by an increase of deferred revenue of $7.5 million associated with the payment received from Actavis in March 2015 partially offset by a decrease in prepaid expenses and other assets of $0.2 million and a decrease in accounts payable and accrued expenses of $1.3 million.

Net cash provided by investing activities

Net cash provided by investing activities for the six months ended June 30, 2016 and 2015 was $17.4 million and $7.3 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 $11.9 million for the six months ended June 30, 2016, which was due to net proceeds of $11.8 million from the sale of common stock through Cowen, pursuant to an ATM sales facility and proceeds from exercises of common stock options.

Net cash provided by financing activities was $16.4 million for the six months ended June 30, 2015, which was due to net proceeds of $16.2 million from the sale of common stock through Cowen, pursuant to an ATM sales facility and proceeds from exercises of common stock options.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses and negative cash flows from operations for the foreseeable future. We expect our cash expenditures to 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 selling and marketing of any future products.

We believe that our cash and cash equivalents and marketable securities as of June 30, 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 June 30, 2016. We may offer and sell shares of our common stock under the existing registration statement (including under our ATM facility) or any registration statement we may file in the future. If we raise additional funds through the issuance of convertible securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations.

Table of Contents

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

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

Option and License Agreements and Other Commitments

For a description of our agreement with Allergan, see "—Option and License Agreements 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.

Table of Contents

Please see the “Critical Accounting Policies and Significant Judgments and Estimates” section of our most recent Annual Report on Form 10-K as filed with the SEC which is incorporated herein by reference, for full detail. We did not make any significant changes to our critical accounting policies during the six months ended June 30, 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 $36.8 million and marketable securities of $107.7 million at June 30, 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 an immediate 10% increase or decrease in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 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.

Table of Contents

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 factors:

Risks Related to Our Financial Position and Capital Needs

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

We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate and continue enrollment in our Phase 3 clinical trials for oliceridine and continue research and development and initiate additional clinical trials of, and seek regulatory approval for, oliceridine and our other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to:

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

We estimate that our existing cash and cash equivalents as of June 30, 2016, together with interest thereon, will enable us to fund our operating expenses and capital expenditure requirements into 2018 Accordingly, we expect that we will need to raise substantial additional funds in the future. Our future capital requirements will depend on many factors, including:

- the progress and results of the Phase 3 clinical program for oliceridine;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates, including our ongoing preclinical work for TRV250;
- our ability to enter into collaborative agreements for the development and commercialization of our product candidates, including oliceridine in regions outside the United States;

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

Table of Contents

· the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, both in the United States and in territories outside the United States.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. Despite these efforts, we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. For example, in May 2016, we announced that TRV027 failed to meet either the primary or secondary endpoints of the BLAST-AHF Phase 2b clinical trial. In addition, our product candidates, if approved, may not achieve commercial success or meet our expectations. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for at least several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

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

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

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

Risks Related to the Discovery and Development of Our Product Candidates

We are very early in our development efforts and have only one product candidate, oliceridine, in Phase 3 clinical trials. If we are unable to successfully complete development and commercialization of our product candidates, either on our own or with a partner, or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have only one product candidate, oliceridine, that recently entered Phase 3 development. We have invested substantially all of our efforts and financial resources in the identification and development of biased ligands. Our ability to generate product revenue, which we do not expect will occur for at least several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

· successful completion of preclinical studies and clinical trials;
· receipt of marketing approvals from applicable regulatory authorities;
·

obtaining, maintaining and protecting our intellectual property portfolio, including patents and trade secrets, and regulatory exclusivity for our product candidates;

- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;

Table of Contents

- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage of our products and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. For example, for oliceridine, enrollment in our Phase 3 program could be impacted by the limited number of sites with experience in recruited surgery models or the number of trials being conducted by others that are testing products in such surgery models. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

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

If our product candidates are associated with adverse side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the compound or significantly limited its commercial opportunity. In the event that our clinical trials reveal a high and unacceptable severity and prevalence of side effects, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

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

could result, including:

Table of Contents

- regulatory authorities may require additional warnings on the label or even withdraw approvals of such product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients, if one is not required before approval;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

Oliceridine and TRV734 are both biased ligands targeted at the μ-opioid receptor. Common adverse reactions for agonists of the μ-opioid receptor include respiratory depression, constipation, nausea, vomiting and addiction. In rare cases, μ-opioid receptor agonists can cause respiratory arrest requiring immediate medical intervention. Since oliceridine and TRV734 also modulate the μ-opioid receptor, these adverse reactions and risks could apply to the use of oliceridine and TRV734. One healthy subject in the 0.25 mg dosing cohort of our Phase 1 clinical trial of oliceridine experienced a severe episode of vasovagal syncope during which he fainted and his pulse stopped. These were considered severe adverse events. It is possible that serious adverse vasovagal events could occur in other patients dosed with oliceridine. Agonists at the -opioid receptor have been associated with a risk of seizures. TRV250, our -opioid receptor product candidate, targets the same receptor as other programs that have been associated with seizures and, accordingly, it is possible that it will be associated with similar side effects.

Risks Related to the Commercialization of Our Product Candidates

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

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

29

Table of Contents

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

For oliceridine, we will need to partner with one or more third parties to sell, market and distribute this product, if approved, outside the United States. We may be unsuccessful in our efforts to secure such partnerships.

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

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

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

Some of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing,

Table of Contents

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

Risks Related to Our Dependence on Third Parties

Any future relationships or collaborations we may enter into may be important to us. If we are unable to maintain our relationship with any of these collaborations, or if our relationship with these collaborators is not successful, our business could be adversely affected.

We have limited capabilities for product development, sales, marketing and distribution. For our product candidates, 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 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.

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;

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collaborators may elect not to continue 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

Table of Contents

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 any 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 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.

We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We have limited internal manufacturing capabilities and do not have any manufacturing facilities. In addition, our product candidates have never been manufactured at commercial scale. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture, if any, of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Table of Contents

We also expect to rely on third party manufacturers or third party collaborators for the manufacture of commercial supply of any product candidates for which our collaborators or we obtain marketing approval. We may be unable to establish any agreements with third party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third party manufacturers, reliance on third party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- manufacturing delays if our third party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

The facilities used by our contract manufacturers to manufacture our product candidates and, potentially in the future, our products must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with current good manufacturing practice, or cGMP, regulations for manufacture of our product candidates. Third party manufacturers may not be able to comply with the cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our product candidates and any products that we may commercialize likely will compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers.

The U.S. Drug Enforcement Administration, or DEA, restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for our μ-opioid receptor targeted product candidates, including oliceridine. In addition, a DEA quota system controls and limits the availability and production of controlled substances and the DEA also has authority to grant or deny requests for quota of controlled substances, which will likely include the active ingredients in oliceridine. Supply disruptions could result from delays in obtaining DEA approvals for controlled substances or from the receipt of quota of controlled substances that are insufficient to meet future product demand. The quota system also may limit our ability to build inventory as a method for mitigating possible supply disruptions if oliceridine is approved for sale in the United States.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential

product revenue.

Table of Contents

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Should we enter into collaborations with third parties, we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of our patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after a first filing, or in some cases at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith Act was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent and Trademark Office continues to develop and implement new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third party preissuance submission of prior art to the United States Patent and Trademark Office, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our

patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Table of Contents

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Exhibit Number	Description
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.

Table of Contents

101* The following financial information from this Quarterly Report on Form 10-Q for the three and six months ended June 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets as of June 30, 2016 and December 31, 2015, (ii) Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2016 and 2015, (iii) Statement of Stockholders' Equity for the period from January 1, 2016 to June 30, 2016, (iv) Statements of Cash Flows for the six months ended June 30, 2016 and 2015 and (v) Notes to Unaudited Financial Statements, tagged as blocks of text.

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

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: August 4, 2016

TREVENA, INC.

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

Table of Contents

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