Trovagene, Inc.
Form 10-Q
May 10, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)
x QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2016

OR
o TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

COMMISSION FILE NUMBER 001-35558

TROVAGENE, INC.
(Exact Name of registrant as specified in its charter)

Delaware	27-2004382
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11055 Flintkote Avenue, Suite B, San Diego, California 92121
(Address of principal executive offices) (Zip Code)

Issuer's telephone Number: (858) 952-7570

Indicate by check mark whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 x No o

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 x No o

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of April 29, 2016, the issuer had 29,861,820 shares of Common Stock issued and outstanding.

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TROVAGENE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	3/31/2016	12/31/2015
Assets		
Current assets:		
Cash and cash equivalents	$59,989,329	$67,493,047
Accounts receivable	61,935	98,736
Prepaid expenses and other assets	840,724	789,285
Total current assets	60,891,988	68,381,068
Property and equipment, net	4,745,781	2,690,579
Other assets	371,243	374,004
Total Assets	$66,009,012	$71,445,651
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,297,306	$1,040,868
Accrued expenses	2,974,493	1,934,411
Current portion of long-term debt	5,850,051	5,225,818
Total current liabilities	10,121,850	8,201,097
Long-term debt, less current portion	10,373,081	11,246,188
Derivative financial instruments	2,763,327	3,297,077
Other liabilities	1,591,306	—
Total Liabilities	24,849,564	22,744,362
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.001 par value, 20,000,000 shares authorized; 60,600 shares outstanding at March 31, 2016 and December 31, 2015; designated as Series A Convertible Preferred Stock with liquidation preference of $606,000 at March 31, 2016 and December 31, 2015	60	60
Common stock, $0.0001 par value, 150,000,000 shares authorized; 29,782,601 and 29,737,601 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	2,979	2,974
Additional paid-in capital	160,312,881	157,585,498
Accumulated other comprehensive loss	(651)	—
Accumulated deficit	(119,155,821)	(108,887,243)
Total stockholders' equity	41,159,448	48,701,289
Total liabilities and stockholders' equity	$66,009,012	$71,445,651

See accompanying notes to the unaudited condensed consolidated financial statements.

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TROVAGENE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Royalty income	$112,868	$124,804
Diagnostic service revenue	7,618	2,166
Total revenues	120,486	126,970
Costs and expenses:		
Cost of revenue	309,271	176,425
Research and development	3,208,064	2,197,659
Selling and marketing	3,057,552	794,653
General and administrative	4,004,247	1,805,985
Total operating expenses	10,579,134	4,974,722
Loss from operations	(10,458,648)	(4,847,752)
Net interest expense	(337,620)	(383,469)
Gain (loss) from change in fair value of derivative instruments — warrants	533,750	(1,946,728)
Other income, net	—	3,568
Net loss	(10,262,518)	(7,174,381)
Preferred stock dividend	(6,060)	(6,060)
Net loss attributable to common stockholders	$(10,268,578)	$(7,180,441)
Net loss per common share — basic	$(0.35)	$(0.33)
Net loss per common share — diluted	$(0.36)	$(0.33)
Weighted average shares outstanding — basic	29,755,184	21,817,710
Weighted average shares outstanding — diluted	30,108,377	21,817,710

See accompanying notes to the unaudited condensed consolidated financial statements.

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OTHETROVAGENE, INC.
CONDENSED CONSOLIDATED STATEMENTS COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Net loss	$(10,262,518)	$(7,174,381)
Other comprehensive loss:		
Foreign currency translation loss	(651)	—
Total other comprehensive loss	(651)	—
Total comprehensive loss	(10,263,169)	(7,174,381)
Preferred stock dividend	(6,060)	(6,060)
Comprehensive loss attributable to common stockholders	$(10,269,229)	$(7,180,441)

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TROVAGENE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Operating activities		
Net loss	$(10,262,518)	$(7,174,381)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net gain on disposal of fixed assets	—	(3,568)
Depreciation and amortization	156,821	68,519
Stock based compensation expense	2,811,108	711,741
Amortization of debt costs	93,062	124,713
Accretion of discount on debt	27,631	28,486
Change in fair value of derivative instruments - warrants	(533,750)	1,946,728
Changes in operating assets and liabilities:		
Decrease in other assets	2,761	—
Decrease (increase) in accounts receivable	36,801	(2,697)
Increase in prepaid expenses	(51,272)	(48,781)
Increase (decrease) in accounts payable and accrued expenses	1,072,343	(383,642)
Decrease in other liabilities	(268,694)	—
Net cash used in operating activities	(6,915,707)	(4,732,882)
Investing activities:		
Capital expenditures, net	(352,023)	(247,097)
Net cash used in investing activities	(352,023)	(247,097)
Financing activities:		
Proceeds from sales of common stock, net of expenses	—	21,445,785
Proceeds from exercise of options	133,613	236,038
Borrowing under equipment line of credit	550,297	—
Repayments of long-term debt	(919,864)	—
Net cash (used in) provided by financing activities	(235,954)	21,681,823
Effect of exchange rate changes on cash and cash equivalents	(34)	—
Net change in cash and equivalents	(7,503,718)	16,701,844
Cash and cash equivalents—Beginning of period	67,493,047	27,293,798
Cash and cash equivalents—End of period	$59,989,329	$43,995,642
Supplementary disclosure of cash flow activity:		
Cash paid for taxes	$—	$800
Cash paid for interest	$276,214	$265,125
Supplemental disclosure of non-cash investing and financing activities:		
Preferred stock dividends accrued	$6,060	$6,060
Leasehold improvements paid for by lessor	$1,860,000	$—

See accompanying notes to the unaudited condensed consolidated financial statements.

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TROVAGENE, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Organization and Basis of Presentation

Business Organization and Overview

Trovagene, Inc. ("Trovagene" or the "Company") is a molecular diagnostic company that focuses on the development and commercialization of a proprietary urine-based cell-free molecular diagnostic technology for use in disease detection and monitoring across a variety of medical disciplines. Trovagene's primary internal focus is to leverage its novel urine-based molecular diagnostic platform to facilitate improvements in the field of oncology, while the Company's external focus includes entering into collaborations to develop the Company's technology in areas such as infectious disease, transplant medicine, and prenatal genetics. The Company's goal is to improve treatment outcomes for cancer patients using its proprietary technology to detect and quantitatively monitor cell-free DNA in urine. Circulating tumor DNA ("ctDNA") is a subtype of cell-free DNA, and represents the mutant cell-free DNA that we use to detect and monitor cancer.

Basis of Presentation

The accompanying consolidated financial statements of Trovagene, which include its wholly owned subsidiary, Trovagene, Srl, a subsidiary formed in Italy, have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All intercompany balances and transactions have been eliminated.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with GAAP and the rules and regulations of the Securities and Exchange Commission ("SEC") related to a quarterly report on Form 10-Q. Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to those rules and regulations. The unaudited interim condensed consolidated financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the results for the periods presented. All such adjustments are of a normal and recurring nature. The operating results presented in these unaudited interim condensed consolidated financial statements are not necessarily indicative of the results that may be expected for any future periods. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2015 included in the Company's annual report on Form 10-K filed with the SEC on March 10, 2016.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

Revenue is recognized when persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

Milestone, Royalty and License Revenues

The Company licenses and sublicenses its patent rights to healthcare companies, medical laboratories and biotechnology partners. These agreements may involve multiple elements such as license fees, royalties and milestone payments. Revenue is recognized when the criteria described above have been met as well as the following:

•Up-front nonrefundable license fees pursuant to agreements under which the Company has no continuing performance obligations are recognized as revenues on the effective date of the agreement and when collection is reasonably assured.

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•Minimum royalties are recognized as earned, and royalties in excess of minimum amounts are recognized upon receipt of payment when collection is assured.

•Milestone payments are recognized when both the milestone is achieved and the related payment is received.

Diagnostic Service Revenues

Revenue for clinical laboratory tests may come from several sources, including commercial third-party payors, such as insurance companies and health maintenance organizations, government payors, such as Medicare and Medicaid in the United States, patient self-pay and, in some cases, from hospitals or referring laboratories who, in turn, might bill third-party payors for testing. The Company is recognizing diagnostic service revenue on the cash collection basis until such time as it is able to properly estimate collections on third party reimbursements.

Derivative Financial Instruments—Warrants

The Company has issued common stock warrants in connection with the execution of certain equity financings. Such warrants are classified as derivative liabilities under the provisions of Financial Accounting Standards Board ("FASB") ASC 815 Derivatives and Hedging ("ASC 815") and are recorded at their fair market value as of each reporting period. Such warrants do not meet the exemption that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified in stockholders' equity. Changes in fair value of derivative liabilities are recorded in the consolidated statement of operations under the caption "Change in fair value of derivative instruments."

The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding the volatility of Trovagene's common share price, the fair value of the underlying common shares, the remaining life of the warrant, and the risk-free interest rates at each period end. The Company thus uses model-derived valuations where inputs are observable in active markets to determine the fair value and accordingly classifies such warrants in Level 3 per ASC 820, Fair Value Measurements. At March 31, 2016, and December 31, 2015, the fair value of these warrants was $2,763,327 and $3,297,077, respectively, and were included in the derivative financial instruments liability on the balance sheet.

Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, Earnings per Share, for all periods presented. In accordance with this guidance, basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Preferred dividends are included in income available to common stockholders in the computation of basic and diluted earnings per share. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common share equivalents are only included when their effect is dilutive.

The following table sets forth the computation of basic and diluted earnings per share:

	Three Months Ended March 31,	
	2016	2015
Numerator: Net loss attributable to common shareholders	$(10,268,578)	$(7,180,441)
Adjustment for change in fair value of derivative instruments - warrants	(533,750)	—
Net loss used for diluted loss per share	$(10,802,328)	$(7,180,441)

Denominator for basic and diluted net loss per share:		
Weighted average shares used to compute basic loss per share	29,755,184	21,817,710
Adjustments to reflect assumed exercise of warrants	353,193	—
Weighted average shares used to compute diluted net loss per share	30,108,377	21,817,710
Net loss per share attributable to common stockholders:		
Basic	$(0.35)	$(0.33)
Diluted	$(0.36)	$(0.33)

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The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their effect was anti-dilutive:

	March 31, 2016	2015
Options to purchase Common Stock	8,117,024	5,875,138
Warrants to purchase Common Stock	4,515,947	5,993,952
Series A Convertible Preferred Stock	63,125	63,125
	12,696,096	11,932,215

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, Leases. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact the adoption of the new standard will have on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements—Going Concern, which impacts the accounting guidance related to the evaluation of an entity's ability to continue as a going concern. The amendment establishes management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern in connection with preparing financial statements for each annual and interim reporting period. The amendment also gives guidance to determine whether to disclose information about relevant conditions and events when there is substantial doubt about an entity's ability to continue as a going concern. The amended guidance is effective prospectively for fiscal years beginning after December 15, 2016. The new guidance is not expected to have a material impact on the Company's financial position, results of operations or cash flows.

In May 2014, the FASB issued ASU 2014-9, Revenue from Contracts with Customers ("ASU 2014-9"). ASU 2014-9 provides companies with a single model for accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the model is to recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. The guidance permits companies to either apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment. In August 2015, the FASB issued ASU 2015-14, Deferral of the Effective Date, which defers the required adoption date of ASU 2014-09 by one year. As a result of the deferred effective date, ASU 2014-09 will be effective for the Company in its first quarter of fiscal year 2018. Early adoption is permitted but not before the original effective date of the first quarter of fiscal year 2017. The Company is in the process of evaluating the transition method that will be elected and the impact of adoption of ASU 2014-09 on its consolidated financial statements.

3. Fair Value Measurements

The following table presents the Company's assets and liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of March 31, 2016 and December 31, 2015:

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	Fair Value Measurements at March 31, 2016			
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market fund (1)	$59,070,272		$—	$59,070,272
Total Assets	$59,070,272	$—	$—	$59,070,272
Liabilities:				
Derivative liabilities related to warrants	$—	$—	$2,763,327	$2,763,327
Total Liabilities	$—	$—	$2,763,327	$2,763,327

	Fair Value Measurements at December 31, 2015			
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market fund (1)	$65,016,222	$—	$—	$65,016,222
Total Assets	$65,016,222	$—	$—	$65,016,222
Liabilities:				
Derivative liabilities related to warrants	$—	$—	$3,297,077	$3,297,077
Total Liabilities	$—	$—	$3,297,077	$3,297,077

(1) Included as a component of cash and cash equivalents on the accompanying condensed consolidated balance sheets.

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the three months ended March 31, 2016:

Description	Balance at December 31, 2015	Unrealized gain	Balance at March 31, 2016
Derivative liabilities related to Warrants	$3,297,077	$(533,750)	$2,763,327

The unrealized loss on the derivative liabilities is recorded as a change in fair value of derivative liabilities in the Company's condensed consolidated statement of operations. 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. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

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4. Property and Equipment

Property and equipment consist of the following:

	As of March 31, 2016	As of December 31, 2015
Furniture and office equipment	$1,509,546	$1,483,227
Leasehold Improvements	1,952,180	39,401
Laboratory equipment	2,294,203	2,022,733
	5,755,929	3,545,361
Less—accumulated depreciation and amortization	(1,010,148)	(854,782)
Property and equipment, net	$4,745,781	$2,690,579

5. Debt

Equipment Line of Credit

In November 2015, the Company entered into a Loan and Security Agreement ("Equipment Line of Credit") with Silicon Valley Bank that provided for cash borrowings for equipment ("Equipment Advances") of up to $2.0 million, secured by the equipment financed. Under the terms of the agreement, interest is equal to 1.25% above the Prime Rate. Interest only payments are due on borrowings through November 30, 2016, with both interest and principal payments commencing in December 2016. Any equipment advances after November 30, 2016 are subject to principal and interest payments immediately over a 36-month period following the advance. All unpaid principal and interest on each Equipment Advance will be due on November 1, 2019. The Company has an obligation to make a final payment equal to 7% of total amounts borrowed at the loan maturity date.

The Company is also subject to certain affirmative and negative covenants under the Equipment Line of Credit. As of March 31, 2016, the Company was in compliance with all covenants.

As of March 31, 2016, $1,636,359 has been borrowed under the Equipment Line of Credit. As of March 31, 2016, amounts due under the Equipment Line of Credit included $181,818 in current liabilities and $1,462,260 in long-term liabilities, which includes $7,719 of accrued final payment. The Company recorded $21,179 in interest expense related to the Equipment Line of Credit during the year ended March 31, 2016.

Future payments of long-term debt at March 31, 2016 are as follows:

2016	$181,818
2017	545,453
2018	545,453
2019	363,635
Total principal	1,636,359
Plus final fee premium accretion	7,719
Total long-term obligations	$1,644,078

Loan and Security Agreement

In June 2014, the Company entered into a $15,000,000 loan and security agreement (“Agreement”) under which the lenders provided the Company a term loan, which was funded at closing. The interest rate is 7.07% per annum. Under the Agreement, the Company made interest only payments on the outstanding amount of the loan on a monthly basis through February 2016, after which equal monthly payments of principal and interest are due until the loan maturity date of July 1, 2018. The loan is secured by a security interest in all of the Company’s assets except intellectual property, which is subject to a negative pledge. In connection with the loan, the lenders received a warrant to purchase an aggregate 85,470 shares of the Company’s common stock at an exercise price of $3.51 per share exercisable for ten years from the date of issuance. The original value of the warrants, totaling $235,857, was recorded as debt discount and additional paid-in capital as the warrants were equity classified. As of March 31, 2016, a warrant to purchase 42,735 shares of common stock remains outstanding.

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At the Company's option, it may prepay all of the outstanding principal balance, subject to certain pre-payment fees ranging from 1% to 3% of the prepayment amount. In the event of a final payment of the loans under the loan agreement, either in the event of repayment of the loan at maturity or upon any prepayment, the Company is obligated to pay the amortized portion of the final fee of $1,050,000.

The Company is also subject to certain affirmative and negative covenants under the Agreement, including limitations on its ability to: undergo certain change of control events; convey, sell, lease, license, transfer or otherwise dispose of any equipment financed by loans under the loan agreement; create, incur, assume, guarantee or be liable with respect to indebtedness, subject to certain exceptions; grant liens on any equipment financed under the loan agreement; and make or permit any payment on specified subordinated debt. In addition, under the Agreement, subject to certain exceptions, the Company is required to maintain with the lender its primary operating, other deposit and securities accounts. Furthermore, under the amendment to the Agreement, the Company is required to be in compliance with healthcare laws and regulations and terms and conditions of healthcare permits. The Company was in compliance with all covenants as of March 31, 2016.

As of March 31, 2016, amounts due under the Agreement include $5,752,026 in current liabilities and $8,827,028 in long-term liabilities, which include $623,182 of accrued final payment. The Company recorded $345,162 in interest expense related to the Agreement during the three months ended March 31, 2016.

Future payments of long-term debt at March 31, 2016 are as follows:

2016	$5,752,026
2017	6,172,134
2018	2,155,976
Total principal	14,080,136
Less discount	(124,264)
Plus final fee premium accretion	623,182
Total long-term obligations	$14,579,054

Debt Agreement

In February 2016, the Company signed a term sheet to refinance its existing term loan in June 2014. Under the term sheet, interest would be equal to 3.75% plus the Wall Street Journal Prime Rate, subject to a floor of 7.25%. Interest only payments would be for 12 months, followed by equal monthly payments of principal and interest over the following 30 months. The Company would also have an obligation to make a final payment equal to 7.50% of total funded amounts at the loan maturity date. In addition, the lenders would receive a warrant to purchase such number of shares of the Company's common stock as is equal to 1% of the funded amount divided by an average closing price of the Company's common stock. As of March 31, 2016, the refinancing documents have not been fully executed.

6. Derivative Financial Instruments — Warrants

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Contracts in Entity's Own Equity, Trovagene determined that certain warrants issued in connection with the execution of certain equity financings must be recorded as derivative liabilities. In accordance with ASC Topic 815-40, the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant change in fair value is being recorded in the Company's statement of operations. The Company estimates the fair value of these warrants using the Black-Scholes option pricing model.

The assumptions used to determine the Black-Scholes fair value of the warrants during the periods indicated were:

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	Three Months Ended March 31,			
	2016		2015	
Estimated fair value of Trovagene common stock	4.65		6.81	
Expected warrant term	2.75 years		3.75 years	
Risk-free interest rate	0.87	%	0.89	%
Expected volatility	81.8	%	75.4	%
Dividend yield	0	%	0	%

Expected volatility is based on the volatility of a peer group of companies with attributes similar to Trovagene. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Trovagene used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates consistent with the expected remaining term of the warrants at each balance sheet date.

The following table sets forth the components of changes in the Company’s derivative financial instruments liability balance, valued using the Black-Scholes option pricing method, for the periods indicated.

Date	Description	Warrants	Derivative Instrument Liability
December 31, 2015	Balance of derivative financial instruments liability	967,297	$3,297,077
	Change in fair value of warrants during the period recognized as a gain in the condensed consolidated statement of operations	—	(533,750)
March 31, 2016	Balance of derivative financial instruments liability	967,297	$2,763,327

7. Stockholders’ Equity

Common Stock

During the three months ended March 31, 2016, the Company issued a total of 45,000 shares of Common Stock, all of which were issued upon exercise of options for a weighted average price of $2.97.

Stock Options

Stock-based compensation expense related to Trovagene options have been recognized in operating results as follow:

	Three Months Ended March 31,	
	2016	2015
Included in research and development expense	$398,741	$289,197
Included in cost of revenue	18,297	26,706
Included in selling and marketing expense	578,721	80,488
Included in general and administrative expense	1,815,349	315,350
Total stock-based compensation expense	$2,811,108	$711,741

The unrecognized compensation cost related to non-vested stock options outstanding at March 31, 2016 and 2015, net of expected forfeitures, was $12,118,815 and $7,715,890, respectively, both to be recognized over a weighted-average remaining vesting period of approximately three years. The weighted average remaining contractual term of outstanding options as of March 31, 2016 was approximately eight years.

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following weighted average assumptions during the following periods indicated:

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	Three Months Ended March 31,	
	2016	2015
Risk-free interest rate	1.48 %	1.77 %
Dividend yield	0 %	0 %
Expected volatility	82 %	75 %
Expected term	5.2 years	6.2 years

A summary of stock option activity and changes in stock options outstanding is presented below:

	Total Options	Weighted Average Exercise Price Per Share	Intrinsic Value
Balance outstanding, December 31, 2015	6,948,630	$ 5.45	$5,903,466
Granted	2,091,950	5.14	
Exercised	(45,000)	2.97	
Canceled / Forfeited	(809,279)	5.36	
Expired	(69,277)	11.01	
Balance outstanding, March 31, 2016	8,117,024	5.35	3,346,992
Exercisable at March 31, 2016	3,533,611	4.59	2,638,307

As of March 31, 2016, the Company had issued 996,000 options to its executive officers and non-employee directors that are over the authorized number of options in the Plan and are subject to shareholder approval. As per ASC Topic 815-40, the options have been accounted for as liabilities and recorded at fair value with the changes in fair value being recorded in the Company’s statement of operations. Once shareholder approval is obtained to increase the number of authorized shares, the liability will then be reversed into additional paid in capital. The Company has recorded a $217,333 liability for this amount in accrued expenses.

The Trovagene Inc. 2014 Equity Incentive Plan (the “2014 EIP”) authorizing up to 2,500,000 shares of common stock for issuance under the Plan was approved by the Board of Directors in June 2014 and approved by the Shareholders at the September 17, 2014 Annual Shareholders’ Meeting. An additional 2,500,000 shares of common stock for issuance was authorized by the Board of Directors in March 2015 and approved by the Shareholders at the June 10, 2015 Annual Shareholders’ Meeting. As of March 31, 2016, excluding the options to purchase an aggregate of 996,000 shares granted to our executive officers and non-employee directors that are subject to stockholder approval, there were 887,911 shares available for issuance under the 2014 EIP. The Company will hold the Annual Shareholders' Meeting on May 17, 2016 to consider and act upon a proposal to approve an amendment to the 2014 EIP to increase the number of shares issuable to 7,500,000 shares from 5,000,000 shares.

Warrants

A summary of warrant activity and changes in warrants outstanding, including both liability and equity classifications is presented below:

	Total Warrants	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2015	5,533,242	$ 3.86	2.5
Exercised	(50,000)	8.00	
Balance outstanding, March 31, 2016	5,483,242	3.82	2.3

8. Commitments and Contingencies

Employment and Consulting Agreements

The Company has longer-term contractual commitments with various consultants and employees. Certain employment agreements provide for severance payments.

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Lease Agreement

The Company currently leases approximately 22,600 square feet of office and laboratory space at a monthly rental rate of approximately $60,000. The lease will expire on December 31, 2021. The Company also leases certain office building in Torino, Italy, consisting of approximately 2,300 square feet at a monthly rental rate of approximately $3,100. The lease is for a period of three years and expires December 31, 2018.

Research and Development Agreements

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. Included in research and development expense, the Company has recorded approximately $317,000 for the three months ended March 31, 2016 relating to services provided by the collaborators in connection with these agreements.

The Company is a party to various agreements under which it licenses technology on an exclusive basis in the field of human diagnostics. License fees are generally calculated as a percentage of product revenues, with rates that vary by agreement. To date, payments have not been material.

Other Matters

The Company may be subject to litigation or administrative proceedings related to our business, such as claims related to employment practices, commercial disputes, or patent infringement. Responding to litigation or administrative proceedings, regardless of whether they have merit, can be expensive and disruptive to normal business operations. We are not able to predict the timing or outcome of these matters.

9. Related Party Transactions

In September 2015, the Company entered into a research agreement with University of Turin (“University”) to collaborate on a program of research to develop, optimize and test molecular profiling tools for plasma and urine ctDNA in cancer. Dr. Alberto Bardelli, the Principal Investigator of the University who oversees this research program is also a member of the Scientific Advisory Board of the Company. Under the agreement, the Company has committed to pay up to $529,000 for the services performed by the University. In addition, the Company may pay royalties to the University on revenue generated by the Company from the commercialization of any tools developed during the collaboration. As of March 31, 2016, the Company has incurred and recorded approximately $146,000 of research and development expenses related to the agreement. No royalty expense has been incurred as of March 31, 2016.

10. Subsequent Events

Employment Agreement

In May 2016, the Company entered into an employment agreement with Mr. William J. Welch in which he agreed to serve as the Chief Executive Officer. The term of the agreement is effective as of May 6, 2016. Mr. Welch’s base compensation is $475,000 per year. Mr. Welch is eligible to receive an annual bonus of up to 50% of his base compensation based on meeting certain performance objectives and bonus criteria. Upon entering the agreement, Mr. Welch was granted an option to purchase 750,000 shares of Common Stock. The options have an exercise price of $4.73 per share and will vest over four years.

If employment is terminated by the Company without cause or by Mr. Welch for good reason, Mr. Welch is entitled to receive a severance payment equal to base compensation for 24 months and the potential bonus and any benefits Mr. Welch would be eligible for during that 24 month period. If the employment is terminated as a result of a change of control, in addition to the severance payment described above, all unvested equity awards would immediately vest and become fully exercisable.

Lease Agreement

On April 4, 2016, the Company entered into an amendment to the lease agreement to add approximately 3,500 square feet of office space at a monthly rental rate of approximately $8,300. The amended lease will expire on December 31, 2021 and is expected to commence at the end of 2016.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding the future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions.

In addition, our business and financial performance may be affected by the factors that are discussed under "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 10, 2016. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should not rely upon forward looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

The following discussion and analysis is qualified in its entirety by, and should be read in conjunction with, the more detailed information set forth in the financial statements and the notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q. This discussion should not be construed to imply that the results discussed herein will necessarily continue into the future, or that any conclusion reached herein will necessarily be indicative of actual operating results in the future. Such discussion represents only the best present assessment of our management.

Overview

We are a molecular diagnostic company that focuses on the development and commercialization of a proprietary urine-based cell-free molecular diagnostic technology for use in disease detection and monitoring across a variety of medical disciplines. Our primary internal focus is to leverage our novel urine-based molecular diagnostic platform to facilitate improvements in the field of oncology, while our external focus includes entering into collaborations to develop the Company's technology in areas such as infectious disease, transplant medicine, and prenatal genetics. Our goal is to improve treatment outcomes for cancer patients using our proprietary technology to detect and quantitatively monitor cell-free DNA in urine.

We are leveraging our proprietary molecular diagnostic technology for the detection of cell-free DNA originating from diseased cell death and that can be isolated and detected from urine, blood, and tissue samples to improve disease management.
These genetic materials are also collectively referred to as "cell-free nucleic acids", which result when cells in the body die and release their DNA contents into the bloodstream. The circulating fragments of genetic material are eventually

filtered through the kidneys and therefore, can be detected and measured in urine. Cell-free nucleic acids can be used as genetic markers of disease. As such, the contents of urine or blood samples represent systemic liquid biopsies that can allow for simple, non-invasive or minimally-invasive sample collection methods. Circulating tumor DNA is a subtype of cell-free DNA, and represents the mutant cell-free DNA that we use to detect and monitor cancer.

Our fundamental ctDNA diagnostic platform, also known as our Precision Cancer Monitoring®, ("PCM") platform is protected by a strong intellectual property portfolio. We have developed significant intellectual property around cell-free nucleic acids in urine, the extraction of cell-free nucleic acids from urine, as well as novel assay designs, particularly our proprietary non-naturally occurring primers. Through this proprietary technology, we believe that we are at the forefront of a shift in the way diagnostic medicine is practiced, using simple, non-invasive or minimally invasive sampling and analysis of nucleic acids, which we believe will ultimately lead to more effective treatment monitoring, better management of serious illnesses such as cancer, and the ability to detect the recurrence of cancer earlier. As of March 31, 2016, our intellectual

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property portfolio consists of 89 issued patents worldwide and over 70 pending patent applications globally. Our patent estate includes intellectual property for the detection of cell-free nucleic acids that pass through the kidney into the urine, as well as their application in specific disease areas, including oncology, infectious disease, transplantation, and prenatal genetics.

We believe that our proprietary PCM platform is uniquely positioned to address a high unmet clinical need in field of oncology. Our PCM platform is designed to offer improved cancer monitoring by tracking and analyzing levels of cell-free DNA from either urine or blood samples, and is intended to provide important clinical information beyond the current standard of care. Using urine as a sample, our cancer monitoring technology enables more frequent, non-invasive monitoring of oncogene mutation status, disease progression and disease recurrence. Our research and development efforts were made commercially feasible following improved next-generation sequencing (“NGS”) technologies which are now available at a significantly lower cost. This combined with our extensive patent portfolio around cell-free DNA in urine gives us a competitive advantage to leverage an emerging trend toward monitoring cancer using ctDNA as a marker of disease status. Our proprietary sample preparation process forms the basis of our PCM platform. It includes novel technology for the extraction and isolation of ctDNA from either a urine or blood sample, proprietary non-naturally occurring primers to enrich the sample for mutant alleles, and the ability to detect nucleic acids of interest using one of several leading gene sequencing technologies such as NGS or droplet digital Polymerase Chain Reaction. We believe that our quantitative ctDNA detection and monitoring platform offers industry leading sensitivity, featuring single nucleic acid molecule detection.

Our PCM platform is poised to overcome a significant clinical dilemma in the area of cancer treatment. Recent scientific evidence supports the molecular basis of cancer, and has resulted in a paradigm shift in the way cancer is treated. Researchers and clinicians are now focused on specific oncogene mutations that are believed to be the molecular drivers of cancer, and, as a result, there is a trend in the pharmaceutical research community toward developing targeted therapies. As such, there is a need for oncologists to have an ability to track the mutational status of their patients, including a given patient’s response to treatments that are designed to target driver oncogene mutations. Current monitoring tools such as imaging procedures, tissue biopsy, and circulating tumor cells are insufficient to meet the challenge of monitoring oncogene mutations. Cancer imaging provides a rough indication of tumor size, but provides no information to oncologists regarding mutational status which is important for the use of molecular targeted therapies. Tissue biopsy usually involves a major surgical procedure and, in many cases, is not repeatable as there are limitations related to tissue access for serial biopsies. In some cases, biopsies may not be feasible, significantly increasing the need to determine mutational status using an alternative method. In addition, tumor heterogeneity can create challenges, as the surgeon may not obtain the proper tissue from the tumor sample. With circulating tumor cells, which are typically measured using blood tests, sensitivity is low, and such tests are technically difficult and can be expensive.

While an improvement over chemotherapy in many cases, targeted drug therapies are not without issues, such as their high cost and potential side effects. In order to measure effectiveness of these therapies, repeated monitoring is needed and imaging and serial biopsies have their challenges or may not be optimal. If resistance develops to a targeted cancer therapy, fast and accurate detection of emerging or changing oncogene mutation status has potential to provide critical information early. Our PCM platform provides a novel solution for early detection of cancer progression using urine, a non-invasive, plentiful sample source. We continue to generate positive data supporting the clinical utility of our technology to monitor cancer using ctDNA.

Our accumulated deficit through March 31, 2016 is $119,155,821. To date, we have generated minimal revenues and expect to incur additional losses to perform further research and development activities and expand commercial operations. During 2016, the following significant activities and events occurred:

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Entered into preferred provider agreements with Stratose, Inc., Multiplan, Inc., Three Rivers Provider Network, Fortified Provider Network, FedMed, Inc., American's Choice Provider Network, and Galaxy Health Network. These combined agreements represent in-network coverage for approximately 160 million covered lives.

- Presented clinical study results at the 2016 American Association for Cancer Research ("AACR") Annual Meeting that demonstrated ctDNA assay performance for detection and monitoring KRAS mutations in urine from patients with advanced cancers.

- We appointed William J. Welch, as our Chief Executive Officer, after announcing the departure of Matthew Posard, Chief Commercial Officer and the termination of Antonius Schuh and Stephen Zaniboni as our previous CEO and CFO, respectively.

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Our product development and commercialization efforts are in their early stages, and we cannot make estimates of the costs or the time our development efforts will take to complete, or the timing and amount of revenues related to the sale of our tests or our diagnostic services and revenues related to our license agreements. The risk of completion of any program is high because of the many uncertainties involved in bringing new diagnostic products to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols and/or Clinical Laboratory Improvement Amendments ("CLIA") requirements, extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses, and competing technologies being developed by organizations with significantly greater resources.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of March 31, 2016.

Critical Accounting Policies

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS of our Annual Report on Form 10-K as of and for the year ended December 31, 2015, filed with the SEC on March 10, 2016. There have been no changes to our critical accounting policies since December 31, 2015.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2016 and 2015

Revenues

Our total revenues were $120,486 and $126,970 for the three months ended March 31, 2016 and 2015, respectively. The components of our revenues were as follows:

	Three Months Ended March 31,		
	2016	2015	Increase (Decrease)
Royalty income	$112,868	$124,804	$ (11,936)
Diagnostic service revenue	7,618	2,166	5,452
Total revenues	$120,486	$126,970	$ (6,484)

The $11,936 decrease in royalty income related primarily to lower receipts of payments in excess of minimum royalties in comparison to the same period of the prior year. Diagnostic service revenue is recognized when payment is received for the test results. There were less payments received for the three months ended March 31, 2015.

We expect our royalty income to fluctuate as the royalties are based on the minimum royalty payments as well as the timing of when payments are received for royalties in excess of minimum royalties. In addition, we expect our diagnostic service revenue to increase in future periods, but as the revenue recognition is based on cash receipts, the timing of these revenues is also uncertain.

Cost of Revenues

Our total cost of revenues was $309,271 for the three months ended March 31, 2016, compared to $176,425 in the same period of 2015. Cost of revenues mainly relates to the costs of our diagnostic service revenues. The costs related

to diagnostic service revenues are recognized at the completion of testing. Due to revenue being recognized when cash is received, costs incurred in one period may relate to revenue recognized in a later period. Gross margins are negative as we begin to build test volume to cover costs associated with running our diagnostic tests as well as inefficiencies in realizing capacity related issues. Increase in cost of revenues for the three months ended March 31, 2016 compared to the same period of last year mainly due to the increased volume of test processed offset by decreased average cost per test. To support the increased volume of tests, we increased the average number of our CLIA headcount from five to ten.

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Research and Development Expenses

Research and development expenses consisted of the following:

	Three Months Ended March 31,		
	2016	2015	Increase
Salaries and staff costs	$1,302,260	$799,942	$502,318
Stock-based compensation	398,741	289,197	109,544
Outside services, consultants and lab supplies	1,181,379	921,016	260,363
Facilities	261,237	148,353	112,884
Travel and scientific conferences	42,410	38,238	4,172
Other	22,037	913	21,124
Total research and development	$3,208,064	$2,197,659	$1,010,405

Research and development expenses increased by $1,010,405 to $3,208,064 for the three months ended March 31, 2016 from $2,197,659 for the same period in 2015. Our costs increased primarily due to the average number of our internal research and development personnel growing from fifteen to thirty. In addition, we purchased additional laboratory equipment, lab supplies and clinical samples to support the number of samples processed and validated in connection with our clinical collaborations as well as the development of our urine collection kit. We utilize our clinical collaborations to provide data that summarizes the accuracy of our tests to detect certain types of cancer in urine samples. We also enter into clinical studies to provide data that supports our technology for the monitoring of responsiveness to therapy and the status of diseases. For the three months ended March 31, 2016 we were a party to twenty-seven active collaborations or studies, while in the same period of 2015 we were a party to twenty-three collaborations or studies. We expect research and development expenses to increase as we expand current collaborations or enter into additional collaborations and further product development.

Selling and Marketing Expenses

Selling and marketing expenses consisted of the following:

	Three Months Ended March 31,		
	2016	2015	Increase/(Decrease)
Salaries and staff costs	$1,408,576	$300,131	$ 1,108,445
Stock-based compensation	578,721	80,488	498,233
Outside services and consultants	356,958	150,680	206,278
Facilities	118,261	58,981	59,280
Trade shows, conferences and marketing	342,173	132,511	209,662
Travel	219,633	33,855	185,778
Other	33,230	38,007	(4,777)
Total sales and marketing	$3,057,552	$794,653	$ 2,262,899

Selling and marketing expenses increased by $2,262,899 to $3,057,552 for the three months ended March 31, 2016 from $794,653 for the same period in 2015. The significant components of the increase were primarily increased salaries and staff costs, stock-based compensation, outside services and consultants and trade shows, conferences and marketing costs. During the three months ended March 31, 2016 we increased the number of our field sales, customer support and marketing personnel, bringing our average headcount to twenty-four from eight in the same period of the prior year. These additions to our commercial team support our sales and marketing activities, resulting in the increase in salaries and staff costs and stock-based compensation. The increase in outside services and consultants is due to our utilization of outside marketing consultants and agents for targeted marketing activities such as social media

engagements and public relations services. We expect our selling and marketing expenses to further increase as we hire additional commercial team members.

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General and Administrative Expenses

General and administrative expenses consisted of the following:

	Three Months Ended March 31,		
	2016	2015	Increase/(Decrease)
Personnel and outside services costs	$1,028,651	$836,222	$ 192,429
Board of Directors' fees	101,995	116,007	(14,012)
Stock-based compensation	1,815,349	315,350	1,499,999
Legal and accounting fees	769,797	306,564	463,233
Facilities and insurance	135,922	114,241	21,681
Travel	76,145	85,452	(9,307)
Fees, licenses, taxes and other	76,388	32,149	44,239
Total general and administrative	$4,004,247	$1,805,985	$ 2,198,262

General and administrative expenses increased by $2,198,262 to $4,004,247 for the three months ended March 31, 2016, from $1,805,985 for the same period in 2015. The significant components of the increase were primarily due to the increase in stock-based compensation. In January 2016, our former CEO was granted a non-qualified stock option to purchase 350,000 shares of Common Stock at an exercise price of $5.18 per share. As the stock option was vested upon grant, the fair value of the option, which approximated $1.2 million was expensed in full in the first quarter of 2016. Legal and accounting fees increased primarily as a result of review of federal and state tax regulations with respect to certain executive compensation and additional legal review of regulatory documents filed with the Securities and Exchange Commission. We expect our general and administrative costs to increase to as our commercial operations and research and development teams grow and if we need to retain additional legal resources.

Net interest Expense

Net interest expense was $337,620 and $383,469 for three months ended March 31, 2016 and 2015, respectively. The decrease of net interest expense is primarily due to the approximately $50,000 increase in interest income. During three months ended March 31, 2016, we maintained a higher cash and cash equivalent balance in the financial institutions as compared to the same period of last year, resulted a higher interest income. We expect our interest expense to increase upon completion of the refinancing of our debt.

Change in Fair Value of Derivative Instruments - Warrants

We have issued securities that are accounted for as derivative liabilities. As of March 31, 2016, the derivative liabilities related to securities issued were revalued to $2,763,327, resulting in an decrease in value of $533,750 from December 31, 2015, based primarily upon the decrease in our stock price from $5.40 at December 31, 2015 to $4.65 at March 31, 2016 as well as the changes in the expected term and risk free interest rates for the expected term. The decrease in value was recorded as a gain from the change in fair value of derivative liabilities in the condensed consolidated statement of operations.

Net Loss

Net loss and per share amounts were as follows:

	Three Months Ended March 31,		
	2016	2015	Increase
Net loss attributable to common shareholders	$(10,268,578)	$(7,180,441)	$3,088,137

Net loss per common share — basic	$(0.35)	$(0.33)	$0.02
Net loss per common share — diluted	$(0.36)	$(0.33)	$0.03
Weighted average shares outstanding — basic	29,755,184	21,817,710	7,937,474
Weighted average shares outstanding — diluted	30,108,377	21,817,710	8,290,667

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The $3,088,137 increase in net loss attributable to common shareholders and $0.02 increase in basic net loss per share in 2016 compared to 2015 was primarily the result of the gain from the change in fair value in derivative liabilities, offset by an increase in operating expenses, compared to the same period in the prior year. Basic net loss per share in 2016 was also impacted by the increase in basic weighted average shares outstanding resulting from the sale and issuance of approximately 4.8 million shares of common stock through underwritten public offering and controlled equity offering through our selling agent, as well as the issuance of approximately 640,000 shares of common stock from the exercise of stock options and warrants.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2016, we had $59,989,329 in cash and cash equivalents. Net cash used in operating activities for the three months ended March 31, 2016 was $6,915,707, compared to $4,732,882 for the three months ended March 31, 2015. Our use of cash was primarily a result of the net loss of $10,262,518 for the three months ended March 31, 2016, adjusted for non-cash items related to stock-based compensation of $2,811,108, amortization of debt costs of $93,062, accretion of discount on debt of $27,631, depreciation and amortization of $156,821, and the loss from the change in fair value of derivatives of $533,750. The changes in our operating assets and liabilities consisted of higher accounts payable and accrued expenses, an increase in prepaid expenses, and decreases in accounts receivable, other assets and other liabilities. At our current and anticipated level of operating loss, we expect to continue to incur an operating cash outflow for the next several years.

Investing activities consisted of net purchases for capital equipment that used $352,023 in cash during the three months ended March 31, 2016, compared to $247,097 for the same period in 2015. We expect to make additional investments in capital equipment in 2016, primarily for laboratory equipment.

Net cash used in financing activities was $235,954 during the three months ended March 31, 2016, compared to $21,681,823 net cash provided by financing activities in 2015. Financing activities during the three months ended March 31, 2016 related primarily to the net payment of long-term debt offset by borrowings under equipment line of credit. Financing activities during the same period of the prior year consisted primarily of proceeds from the sale of our common stock in underwritten public offerings. We expect to complete a refinancing of our debt in 2016 that if completed, will result in additional cash provided by financing activities.

As of March 31, 2016, and December 31, 2015, we had working capital of $50,770,138 and $60,179,971, respectively. As of April 30, 2016, our working capital was approximately $47.5 million.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of our research and development programs and ramp up of our sales and marketing function. To date, our sources of cash have been primarily limited to the sale of equity securities and debentures and borrowings under debt agreements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more of product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

CONTRACTUAL OBLIGATIONS

For a discussion of our contractual obligations see (i) our Financial Statements and Notes to Consolidated Financial Statements Note 9. Commitments and Contingencies, and (ii) Item 7 Management Discussion and Analysis of Financial Condition and Results of Operations — Contractual Obligations and Commitments, included in our Annual Report on Form 10-K as of December 31, 2015.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash and cash equivalent primary consists of deposits, and money market deposits managed by commercial banks. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in short-term money marketable funds. Due to the short-term duration of our investment portfolio and the relatively low risk profile of our investments, a sudden change in interest rates would not have a material effect on the fair market value of our portfolio, nor our operating results or cash flows.

We do not believe our cash and cash equivalents have significant risk of default or illiquidity, however, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the current stability of financial institutions, we believe that we will not experience losses on these deposits.

Increase in our vulnerability to interest rate fluctuations is also a result to the extent a portion of our debt has a floating interest rate. Changes in interest rates could affect the amounts of interest that we pay in the future.

Foreign Currency Exchange Risk

Our foreign currency exchange risk arises from our operations in Italy. Our functional and reporting currency is the United States dollar. We translate our foreign operations' assets and liabilities denominated in foreign currencies into U.S. dollars at current rates of exchange as of the balance sheet date and income and expense items at the average exchange rate for the reporting period. Translation adjustments resulting from exchange rate fluctuations are recorded in the cumulative translation account, a component of accumulated other comprehensive income. Gains or losses from foreign currency transactions are included in other expense (income), net.

Effects of Inflation

We do not believe that inflation and changing prices during the three months ended March 31, 2016 had a significant impact on our results of operations.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We have performed an evaluation under the supervision and with the participation of our management, including our principal executive and financial officer, of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"). Based on that evaluation, our CEO and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2016 to provide reasonable assurance that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives as specified above. Management does not expect, however, that our disclosure controls and procedures will prevent or detect all errors and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the three months ended March 31, 2016 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any pending legal proceeding, nor is our property the subject of a pending legal proceeding, that is not in the ordinary course of business or otherwise material to the financial condition of our business, except for the following: On March 28, 2016 we filed a complaint against Dr. Schuh and Mr. Zaniboni, for, among other things, breach of fiduciary duty. The complaint was filed in the Superior Court of the State of California for the County of San Diego. We are alleging that Dr. Schuh and Mr. Zaniboni failed to present a lucrative corporate opportunity to us concerning promising new therapeutics in the field of precision medicine and instead took that opportunity for their own personal benefit. The complaint asks that Dr. Schuh and Mr. Zaniboni be required to turn over their interests in these new therapeutics to us.

On April 29, 2016, a complaint was filed against William J. Welch, our CEO, and our company by Pathway Genomics Corporation alleging, among other things, breach of contract and intentional interference with contractual relations. We believe the complaint is unfounded, and consists largely of baseless speculation that is contrary to fact. We plan to vigorously defend against these allegations.

ITEM 1A. RISK FACTORS

Except for the following risk factors, there have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2015.

We depend upon our officers and other key employees, and if we are not able to retain them or recruit additional qualified personnel, the commercialization of our product candidates and any future tests that we develop could be delayed or negatively impacted.

Our success is largely dependent upon the continued contributions of our officers, especially William J. Welch, our Chief Executive Officer, and other key employees. Our success also depends in part on our ability to retain our current employee base and continue to attract highly qualified scientific, commercial and administrative personnel. The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field and, in order to pursue our test development and commercialization strategies, we will need to attract, hire and retain, or engage as consultants, additional personnel with specialized experience in a number of disciplines, including assay development, bioinformatics and statistics, laboratory and clinical operations, clinical affairs and studies, government regulation, sales and marketing, billing and reimbursement and information systems. Additionally, there is intense competition for personnel in the fields in which we operate. If we are unable to attract new employees and retain existing employees, the development and commercialization of our product candidates and any tests we may develop in the future could be delayed or negatively impacted

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of March 31, 2016, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially owned approximately 30.1% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

•delaying, deferring or preventing a change in control of our company;

•impeding a merger, consolidation, takeover or other business combination involving us; or

•discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit
10.33+	Employment Agreement, dated as of February 18, 2016, by and between Trovagene, Inc. and Mark Erlander.
10.34+	Employment Agreement, dated as of February 18, 2016, by and between Trovagene, Inc. and Matthew Posard.
10.35+	Form of Employment Agreement by and between Trovagene, Inc. and William J. Welch.
10.36+	Form of Indemnification Agreement, dated as of May 6, 2016, by and between Trovagene, Inc. and William J. Welch.
31.1	Certification of Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2016 filed on May 10, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the Condensed Consolidated Financial Statements tagged as blocks of text.

+ Indicates a management contract or compensatory plan or arrangement.

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SIGNATURES

Pursuant to the requirements 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.

TROVAGENE, INC.

Date: May 10, 2016 By: /s/ William J. Welch
William J. Welch
Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)