

Trovogene, Inc.  
Form 10-Q  
May 05, 2015  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-Q**

(Mark One)

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2015

OR

**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 small business issuer as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**27-2004382**  
(I.R.S. Employer  
Identification No.)

**11055 Flintkote Avenue, Suite A, 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  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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

As of April 30, 2015 the issuer had 24,455,107 shares of Common Stock issued and outstanding.



Table of Contents

**TROVAGENE, INC.**

**Table of Contents**

	<b>Page</b>
<b>PART I</b>	<b>FINANCIAL INFORMATION</b>
Item 1:	Financial Statements
	<u>Condensed Consolidated Balance Sheets (unaudited) as of March 31, 2015 and December 31, 2014</u>
	3
	<u>Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2015 and 2014</u>
	4
	<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2015 and 2014</u>
	5
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>
	6
<u>Item 2:</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
	15
<u>Item 3:</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	21
<u>Item 4:</u>	<u>Controls and Procedures</u>
	21
<b><u>PART II</u></b>	<b><u>OTHER INFORMATION</u></b>
<u>Item 6:</u>	<u>Exhibits</u>
	22
<u>SIGNATURES</u>	

Table of Contents**TROVAGENE, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited)**

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 43,995,642	\$ 27,293,798
Accounts receivable	59,391	56,694
Prepaid expenses and other assets	418,040	369,259
Total current assets	44,473,073	27,719,751
Property and equipment, net	1,022,534	840,387
Other assets	336,708	336,708
Total Assets	\$ 45,832,315	\$ 28,896,846
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 484,709	\$ 747,799
Accrued expenses	1,755,803	1,841,808
Current portion of long-term debt	3,064,734	1,898,548
Total current liabilities	5,305,246	4,488,155
Long-term debt, less current portion	12,011,645	13,053,117
Derivative financial instruments	4,952,749	3,006,021
Total Liabilities	22,269,640	20,547,293
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, 2015 and December 31, 2014; designated as Series A Convertible Preferred Stock with liquidation preference of \$606,000 at March 31, 2015 and December 31, 2014	60	60
Common stock, \$0.0001 par value, 150,000,000 shares authorized; 24,307,291, and 18,902,782 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	2,431	1,891
Additional paid-in capital	112,132,535	89,739,511
Accumulated deficit	(88,572,351)	(81,391,909)
Total stockholders' equity	23,562,675	8,349,553
Total liabilities and stockholders' equity	\$ 45,832,315	\$ 28,896,846

See accompanying notes to the unaudited condensed consolidated financial statements.



Table of Contents**TROVAGENE, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Royalty income	\$ 124,804	\$ 110,953
Diagnostic service revenue	2,166	
Total revenues	126,970	110,953
Costs and expenses:		
Cost of revenue	176,425	
Research and development	2,197,659	1,442,521
Selling and marketing	794,653	569,590
General and administrative	1,805,985	1,358,480
Total operating expenses	4,974,722	3,370,591
Loss from operations	(4,847,752)	(3,259,638)
Interest income	6,369	2,391
Interest expense	(389,838)	(9,496)
Gain on disposal of equipment	3,568	44,101
(Loss) gain from change in fair value of derivative instruments warrants	(1,946,728)	32,846
Net loss and comprehensive loss	(7,174,381)	(3,189,796)
Preferred stock dividend	(6,060)	(9,210)
Net loss and comprehensive loss attributable to common stockholders	\$ (7,180,441)	\$ (3,199,006)
Net loss per common share - basic and diluted	\$ (0.33)	\$ (0.17)
Weighted average shares outstanding - basic and diluted	21,817,710	18,902,782

See accompanying notes to the unaudited condensed consolidated financial statements.

Table of Contents**TROVAGENE, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Operating activities:</b>		
Net loss	\$ (7,174,381)	(3,189,796)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Gain on disposal of fixed assets	(3,568)	(44,101)
Depreciation and amortization	68,519	53,528
Stock based compensation expense	711,741	559,773
Amortization of debt costs	124,713	
Accretion of discount on debt	28,486	
Loss (gain) from the change in fair value of derivative instruments - warrants	1,946,728	(32,846)
<b>Changes in operating assets and liabilities:</b>		
Increase in accounts receivable	(2,697)	(50,309)
Increase in prepaid expenses	(48,781)	(109,399)
(Decrease) increase in accounts payable and accrued expenses	(383,642)	14,479
Net cash used in operating activities	(4,732,882)	(2,798,671)
<b>Investing activities:</b>		
Capital expenditures, net of proceeds from disposals	(247,097)	(118,507)
Net cash used in investing activities	(247,097)	(118,507)
<b>Financing activities:</b>		
Proceeds of sale of common stock, net of expenses	21,445,785	
Proceeds from exercise of options	236,038	
Repayments of debt outstanding under equipment line of credit		(48,637)
Net cash provided by (used in) financing activities	21,681,823	(48,637)
Net change in cash and equivalents	16,701,844	(2,965,815)
Cash and cash equivalents Beginning of period	27,293,798	25,836,937
Cash and cash equivalents End of period	\$ 43,995,642	22,871,122
<b>Supplementary disclosure of cash flow activity:</b>		
Cash paid for taxes	\$ 800	\$ 2,400
Cash paid for interest	\$ 265,125	\$ 6,601
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Preferred stock dividends accrued	\$ 6,060	\$ 9,210

See accompanying notes to the unaudited condensed consolidated financial statements.



Table of Contents

**TROVAGENE, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Organization and Basis of Presentation**

*Business Organization and Overview*

On April 26, 2002, the Company was incorporated in the State of Florida. On July 2, 2004, the Company acquired Xenomics, a California corporation, which was in business to develop and commercialize urine-based molecular diagnostics technology. In 2007, the Company changed its fiscal year end from January 31 to December 31. In January 2010, the Company re-domesticated its state of incorporation from Florida to Delaware and the name was changed to Trovogene, Inc. In June 2012, the Company's common stock was listed on The NASDAQ Capital Market under the ticker symbol TROV.

Trovogene, Inc. (Trovogene 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. Trovogene'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 Trovogene, which include its wholly owned subsidiaries Xenomics, Inc., a California corporation, Xenomics Europa Ltd, (an inactive subsidiary formed in the United Kingdom and liquidated) and Etherogen, Inc., a Delaware corporation, 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 U.S. generally accepted accounting principles (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

## Edgar Filing: Trovogene, Inc. - Form 10-Q

year ended December 31, 2014 included in the Company's annual report on Form 10-K filed with the SEC on March 12, 2015.

### **2. Summary of Significant Accounting Policies**

#### *Use of Estimates*

The preparation of financial statements in conformity with U.S. 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.

Table of Contents

*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.
- 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, bill third-party payors for testing.

Diagnostic services revenue is recognized when the criteria described above has been met as well as upon cash collection until the Company can reliably estimate the amount that will be ultimately collected for our LDTs, at which time the Company will recognize diagnostic services revenues on an accrual basis.

*Derivative Financial Instruments Warrants*

## Edgar Filing: Trovogene, Inc. - Form 10-Q

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 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 volatility of Trovogene's common share price, remaining life of the warrant, and 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, 2015, and December 31, 2014, the fair value of these warrants was \$4,952,749 and \$3,006,021, respectively, and were included in the derivative financial instruments liability on the balance sheet.

Table of Contents

*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

## Edgar Filing: Trovogene, Inc. - Form 10-Q

### Table of Contents

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. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

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

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Numerator:</b>		
Net loss attributable to common shareholders	\$ (7,180,441)	\$ (3,199,006)
<b>Denominator for basic and diluted net loss per share:</b>		
Weighted average shares - basic and diluted	21,817,710	18,902,782
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.33)	(0.17)

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive:

	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
Options to purchase Common Stock	5,875,138	4,423,638
Warrants to purchase Common stock	5,993,952	6,233,483
Series A Convertible Preferred Stock	63,125	63,125
	11,932,215	10,720,246

### *Recent Accounting Pronouncements*

In April 2015, a new accounting standard was issued that amends the presentation for debt issuance costs. Upon adoption, such costs shall be presented on our consolidated balance sheets as a direct deduction from the carrying amount of the related debt liability and not as a deferred charge presented in Other assets on our consolidated balance sheets. This new standard will be effective for interim and annual periods beginning on January 1, 2016, and is required to be retrospectively adopted. Adoption of this new standard is not expected to have a material impact on our consolidated balance sheets or related disclosures.

In August 2014, the FASB issued an amendment to the accounting guidance related to the evaluation of an entity 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 will not have an impact on the Company's financial position, results of operations or cash flows.



Table of Contents

In May 2014, the FASB issued Accounting Standards Update ( ASU ) No. 2014-09, Revenue from Contracts with Customers ( ASU 2014-09 ). The standard 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. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016. Early adoption is not permitted. 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. The Company is in the process of evaluating the impact of adoption 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, 2015 and December 31, 2014:

	Fair Value Measurements at March 31, 2015			Total
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>				
Money market fund (1)	\$ 43,979,103	\$	\$	\$
Total Assets	\$ 43,979,103	\$	\$	\$
<b>Liabilities:</b>				
Derivative liabilities related to warrants	\$	\$	\$ 4,952,749	\$ 4,952,749
Total Liabilities	\$	\$	\$ 4,952,749	\$ 4,952,749

	Fair Value Measurements at December 31, 2014			Total
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>				
Money market fund (1)	\$ 27,123,587	\$	\$	\$ 27,123,587
Total Assets	\$ 27,123,587	\$	\$	\$ 27,123,587
<b>Liabilities:</b>				
Derivative liabilities related to warrants	\$	\$	\$ 3,006,021	\$ 3,006,021
Total Liabilities	\$	\$	\$ 3,006,021	\$ 3,006,021

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





Table of Contents

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, 2015:

Description	Balance at		Unrealized	Balance at		
	December 31,			March 31,		
	2014		Loss	2015		
Derivative liabilities related to Warrants	\$	3,006,021	\$	1,946,728	\$	4,952,749

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.

#### 4. Property and Equipment

Property and equipment consist of the following:

	As of March 31,		As of December, 31	
	2015		2014	
Furniture and office equipment	\$	410,660	\$	365,954
Leasehold Improvements		39,401		39,401
Laboratory equipment		1,132,157		968,901
		1,582,218		1,374,256
Less accumulated depreciation and amortization		(559,684)		(533,869)
Property and equipment, net		1,022,534	\$	840,387

#### 5. Debt

##### *Equipment Line of Credit*

In June 2013, the Company entered into a Loan and Security Agreement ( Equipment Line of Credit ) with Silicon Valley Bank that provided for cash borrowings for equipment of up to \$1.0 million, secured by the equipment financed. Under the terms of the agreement, interest was the greater of 5% or 4.6% above the U.S. Treasury Note as of the date of each borrowing. Interest only payments were due on borrowings through December 31, 2013, with both interest and principal payments commencing in January 2014. Any equipment advances after December 31, 2013 were subject to principal and interest payments immediately over a 30 month period following the advance. In June 2014, the equipment loan was paid in full, the Company had no further obligations thereunder, and the bank released its security interest in such assets.

## Edgar Filing: Trovogene, Inc. - Form 10-Q

The Company recorded approximately \$9,500 in interest expense related to the equipment line of credit during the three months ended March 31, 2014.

### *Loan and Security Agreement*

In June 2014, the Company entered into a \$15,000,000 loan and security agreement with two banks pursuant to which the lenders provided the Company a term loan, which was funded at closing. The interest rate on such loan is 7.07% per annum. The Company will make interest only payments on the outstanding amount of the loan on a monthly basis through July 2015, 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.

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 loan 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 loan agreement, subject to certain exceptions, the Company is required to maintain with the lender its primary operating, other deposit and securities accounts. The Company was in compliance with all covenants as of March 31, 2015.

## Edgar Filing: Trovogene, Inc. - Form 10-Q

### Table of Contents

As of March 31, 2015, amounts due under the agreement include 3,064,734 in current liabilities and \$12,011,645 in long-term liabilities. The Company recorded \$389,838 in interest expense related to the loan and security agreement during the three months ended March 31, 2015.

Future minimum principal payments under the loan and security agreement are as follows:

<b>March 31,</b>	
2015	\$ 3,064,734
2016	4,875,802
2017	5,231,914
2018	1,827,550
Total long-term obligations	\$ 15,000,000

### **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, Trovogene has determined that certain warrants issued in connection with the private placements must be recorded as derivative liabilities with a charge to additional paid in capital as they were issued with other equity instruments. 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 (i) certain of these warrants using the Black-Scholes option pricing model and (ii) estimates the fair value of the price protected units using the Binomial option pricing model in order to determine the associated derivative instrument liability and change in fair value described above.

The range of assumptions used to determine the fair value of the warrants valued using the Black-Scholes option pricing model during the periods indicated was:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
Estimated fair value of Trovogene common stock	\$ 6.81	\$ 5.73
Expected warrant term	3.75 years	4.75 years
Risk-free interest rate	0.89%	1.73%
Expected volatility	75.40%	83.0%
Dividend yield	0%	0%

Expected volatility is based on the volatility of a peer group of companies with attributes similar to Trovogene. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Trovogene 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.

## Edgar Filing: Trovogene, Inc. - Form 10-Q

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. For the period ending December 31, 2013, the derivative financial instruments liability in the table below only represents the Black-Scholes calculation whereas the loss recognized in the Statement of Operations represents both the Black-Scholes and the binomial methodology.

Date	Description	Warrants	Derivative Instrument Liability
December 31, 2014	Balance of derivative financial instruments liability	1,013,961	\$ 3,006,021
	Change in fair value of warrants during the period recognized as a loss in the condensed consolidated statement of operations		1,946,728
March 31, 2015	Balance of derivative financial instruments liability	1,013,961	\$ 4,952,749

Table of Contents**7. Stockholders Equity*****Common Stock***

On January 25, 2013, the Company filed a Form S-3 Registration Statement to offer and sell in one or more offerings, any combination of common stock, preferred stock, warrants, or units having an aggregate initial offering price not exceeding \$150,000,000. The preferred stock, warrants, and units may be convertible or exercisable or exchangeable for common stock or preferred stock or other Trovogene securities. This form was declared effective on February 4, 2013. In addition, in connection with the Form S-3, the Company entered into an agreement with Cantor Fitzgerald & Co. ( Agent ) on January 25, 2013 to issue and sell up to \$30,000,000 of shares of common stock through them. As payment for its services, the Agent is entitled to a 3% commission on gross proceeds.

During the three month period ended March 31, 2015, the Company issued a total of 5,391,497 shares of Common Stock. The Company received gross proceeds of approximately \$23.0 million from the sale of 5,111,110 shares of its common stock through an underwritten public offering in February 2015. In addition, the Company received gross proceeds of approximately \$312,000 from the sale of 50,011 shares of its common stock under the agreement with the Agent. In addition, 66,750 shares were issued upon exercise of options for a weighted average price of \$3.54 and 163,626 shares were issued upon net exercise of 271,668 warrants at an exercise price of \$3.00.

***Stock Options***

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

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Included in research and development expense	\$ 289,197	189,635
Included in cost of revenue	26,706	
Included in selling and marketing expense	80,488	22,680
Included in general and administrative expense	315,350	347,458
Total stock-based compensation expense	\$ 711,741	\$ 559,773

The unrecognized compensation cost related to non-vested stock options outstanding at March 31, 2015 and 2014, net of expected forfeitures, was \$7,715,890 and \$3,695,076, 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, 2015 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 assumptions during the following periods indicated:

Edgar Filing: Trovogene, Inc. - Form 10-Q

	Three Months Ended			
	March 31,		2014	
	2015		2014	
Risk-free interest rate	1.6	1.9%	1.5	1.6%
Dividend yield		0%		0%
Expected volatility		75%		83%
Expected term (in years)		6 yrs		5 yrs

## Edgar Filing: Trovogene, Inc. - Form 10-Q

### Table of Contents

A summary of stock option activity and of changes in stock options outstanding under the Trovogene Stock Option Plan is presented below:

	<b>Total Options</b>	<b>Weighted Average Exercise Price Per Share</b>	<b>Intrinsic Value</b>
Balance outstanding, December 31, 2014	4,913,472	\$ 4.66	2,808,083
Granted	1,080,000	6.35	
Exercised	(66,750)	3.54	
Cancelled / Forfeited	(31,250)	6.08	
Expired	(20,334)	11.93	
Balance outstanding, March 31, 2015	5,875,138	4.95	12,559,574
Exercisable at March 31, 2015	2,497,571	4.69	6,659,481

The Trovogene 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. As of March 31, 2015 there are 297,832 shares available for issuance under the 2014 EIP.

### **Warrants**

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

	<b>Total Warrants</b>	<b>Weighted Average Exercise Price Per Share</b>	<b>Weighted Average Remaining Contractual Term</b>
Balance outstanding, December 31, 2014	6,265,620	\$ 3.85	3.57
Granted			
Exercised	(271,668)	3.00	
Balance outstanding, March 31, 2015	5,993,952	3.89	3.31

### **8. Commitments and Contingencies**

#### *Executive and Consulting Agreements*

The Company has longer-term contractual commitments with various consultants and employees, including the Company's Chief Executive Officer ( CEO ) and Chief Financial Officer ( CFO ). The executive agreements with the CEO and CFO provide for severance payments.



*Lease Agreement*

The Company leases approximately 13,000 square feet of office space at a monthly rental rate of approximately \$30,000 for the remaining term of the lease through December 2017.

*Research and Development Agreements*

During 2012, the Company entered into research agreements with University of Texas MD Anderson Cancer Center ( MDACC ) to provide samples and evaluate methods used by the Company in identification of pancreatic cancer mutations, as well as to measure the degree of concordance between results of cell-free DNA mutations analysis from urine samples and tumor tissue. During 2013, the agreements were amended to increase the scope of the agreements. Under these agreements, the Company has committed to pay approximately \$266,000 for the services performed by MDACC. As of March 31, 2015, the Company has incurred and recorded approximately \$283,000 of research and development expenses related to these agreements.

In June 2013, the Company entered into a research agreement with Illumina, Inc. ( Illumina ) pursuant to which the parties will work together to evaluate the potential for integrating the Company's transrenal technology for isolating, extracting and genetic analysis of nucleic acids from urine with Illumina's genetic analysis sequencing technology (the Research Plan ). The parties have agreed that all results and reagents from the Research Plan will be shared between the parties. The agreement will terminate upon the earlier of 30 days after completion of the research plan or the one year anniversary of the agreement unless extended by mutual written agreement. In October 2014, the agreement was extended to June 2015.

## Edgar Filing: Trovogene, Inc. - Form 10-Q

### Table of Contents

In August 2013, the Company entered into a clinical trial agreement with the University of Southern California ( USC ), pursuant to which USC will provide the principal investigator and conduct the clinical trial related to the genetic characterization of metastatic colorectal cancers. Under the agreement, the Company may pay USC approximately \$277,000 for services provided. Through March 31, 2015 the Company has incurred and recorded approximately \$48,000 of research and development expense related to this agreement.

In December 2013, the Company entered into a clinical trial agreement with US Oncology Research LLC ( USOR ), pursuant to which USOR will provide the principal investigator and conduct the clinical trial related to the examining the utility of transrenal quantitative KRAS testing in disease monitoring in patients with metastatic pancreatic cancer. Under the agreement, the Company may pay USOR approximately \$270,000 for services provided. As of March 31, 2015 the Company has incurred and recorded approximately \$44,000 of research and development expense related to this agreement.

In May 2014, the Company entered into a Strategic Research Alliance with the Robert H. Lurie Comprehensive Cancer Center of Northwestern University to conduct one or more research agreements to evaluate use of Trovogene s precision cancer monitoring technology in the management of cancer patients. Under the agreement, each party will be responsible for its own costs and obligations under each agreement. As of March 31, 2015, no costs have been incurred related to this agreement.

In June 2014, the Company entered into a Sponsored Research Agreement with Dana Farber Cancer Institute to conduct a clinical study to evaluate use of Trovogene s precision cancer monitoring technology in the management of lung cancer patients. Under the agreement, Trovogene may pay the collaborator in the study approximately \$42,000 for services provided. As of March 31, 2015, costs of approximately \$10,000 have been incurred related to this agreement.

In June 2014, the Company entered into a Sponsored Research Agreement with Memorial Sloan Cancer Center to conduct a clinical study for the detection of oncogenic tumor mutations in the urine of lung cancer patients. Under the agreement with Memorial Sloan Kettering, Trovogene may pay them approximately \$146,000 for services provided. As of March 31, 2015 the Company has incurred approximately \$43,000 related to this agreement.

In September 2014, under the strategic partnership the Company established in March 2014, the Company entered into a Sponsored Research Agreement with Catholic Health Initiatives Center for Translational Research to conduct clinical studies to evaluate use of Trovogene s PCM technology in the management of cancer patients. Under the terms of the agreement, Trovogene may pay the collaborator up to approximately \$151,000 for services provided. As of March 31, 2015 the Company has incurred approximately \$61,000 related to this agreement.

In October 2014, the Company entered into a Research Agreement with Genomac International, Ltd., for two clinical studies for the early detection of emerging oncogene mutations indicative of resistance to targeted therapies used to treat colorectal and lung cancer. Pursuant to the Research Agreement, Genomac will conduct a research study of minimally invasive molecular monitoring of efficiency of targeted biological therapy in advanced non-small lung cancer. The Company is committed to pay Genomac approximately \$175,000 for services provided. As of March 31, 2015, the Company had incurred and recorded approximately \$90,000 of research and development expenses.

In December 2014, the Company entered into a clinical collaboration with City of Hope to conduct studies to determine the clinical utility of detecting and monitoring EGFR mutations in lung cancer patients using the Company s Precision Cancer Monitoring platform. The Company is

## Edgar Filing: Trovogene, Inc. - Form 10-Q

committed to pay the City of Hope approximately \$114,000 for services provided. As of March 31, 2015, the Company had incurred and recorded approximately \$17,000 related to this agreement.

### 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.

Table of Contents

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, 2014, filed on March 12, 2015. 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 its 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 its 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 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 ( ctDNA ) 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<sup>SM</sup> platform, ( 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, 2015, our intellectual property portfolio consists of over 50 issued patents and over 60 pending patent applications globally. Our patent estate includes 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 cell-free DNA 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 sequence nucleic acids of interest using one of several leading gene sequencing technologies such as NGS or droplet digital PCR. 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

Table of Contents

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 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 is important, 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 effect. 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 mutations can 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 build a growing body of evidence supporting the clinical utility of our technology to monitor cancer using ctDNA.

Our accumulated deficit through March 31, 2015 is \$88,572,351. To date, we have generated minimal revenues and expect to incur additional losses to perform further research and development activities and commercial expansion. During 2015, we have advanced our business with the following activities:

- We closed an underwritten public offering of 5,111,110 shares of common stock with net proceeds of approximately \$21.3 million.
- We recruited Matthew Posard to our Executive Management Team as Chief Commercial Officer to lead our commercial operations.
- We entered into a clinical collaboration with University of California, San Diego Moores Cancer Center to determine the utility of detecting and monitoring *EGFR* mutations in lung cancer patients using our PCM platform.
- We entered into a clinical collaboration with City of Hope to conduct studies to determine the clinical utility of detecting and monitoring *EGFR* mutations in lung cancer patients using our PCM platform.
- Two sets of clinical study results were presented at the 2015 Gastrointestinal Cancer Symposium supporting the utility of our PCM Platform in colorectal and pancreatic cancer patients. Results demonstrated the ability of our PCM platform to detect and quantitate *KRAS* mutations at diagnosis and longitudinally in ctDNA obtained from colorectal and pancreatic cancer patients. We also showed data demonstrating that our proprietary *KRAS* assay can enable physicians to determine mutational status, monitor treatment response, and use genomics to aid in predicting patient prognosis.

## Edgar Filing: Trovogene, Inc. - Form 10-Q

- Clinical study results were presented by Hatim Husain, M.D., from the University of California, San Diego Moores Cancer Center at the 2015 European Lung Cancer Conference. Results demonstrated that our urinary ctDNA assay outperformed tissue biopsy in a clinical study for the detection of *EGFR T790M* mutations in metastatic lung cancer patients. In addition, the study demonstrated that our non-invasive liquid biopsy enables detection of emerging *T790M* mutations with greater sensitivity than tissue biopsy and months before detection of cancer progression with imaging. We also showed that tracking ctDNA in urine enables determination of response to novel *EGFR T790M* inhibitors within days of initial treatment.
- Two sets of clinical study results and one set of analytical data were presented at the 2015 American Association for Cancer Research (AACR) Annual Meeting that demonstrated clinical utilities and advantages of our PCM Platform. The Company's liquid biopsy technology features single molecule sensitivity and the ability to obtain significantly more ctDNA from urine samples vs. plasma.
- Clinical results from the PREDICTORS 4 trial were presented by Jack Cuzick, Ph.D., Director, Wolfson Institute of Preventive Medicine and Head, Centre for Cancer Prevention at Queen Mary University of London at the European Research Organization on Genital Infection and Neoplasia (EUROGIN) 2015 Congress. Results demonstrated high sensitivity for our non-invasive, urine-based HPV assay when determining high-risk human papillomavirus (HPV) types and cervical lesions or cervical intraepithelial neoplasia (CIN) Grade 2/3.

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 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 CLIA requirements, the 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.

Table of Contents**Off-Balance Sheet Arrangements**

We had no off-balance sheet arrangements as of March 31, 2015.

**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, 2014, filed with the SEC on March 12, 2015. There have been no changes to our critical accounting policies since December 31, 2014.

**RESULTS OF OPERATIONS****Three Months Ended March 31, 2015 and 2014***Revenues*

Our total revenues were \$126,970 and \$110,953 for the three months ended March 31, 2015 and 2014, respectively. The components of our revenues were as follows:

	<b>Three Months Ended March 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>Increase (Decrease)</b>
Royalty income	\$ 124,804	\$ 110,953	13,851
Diagnostic service revenue	2,166		2,166
Total revenues	\$ 126,970	\$ 110,953	16,017

The \$13,851 increase in royalty income related primarily to receipts of payments in excess of minimum royalties. Diagnostic service revenue recognized when payment is received for the test results. There was no diagnostic service revenue for the three months ended March 31, 2014 as no payments were received.

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



## Edgar Filing: Trovogene, Inc. - Form 10-Q

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 \$176,425 for the three months ended March 31, 2015, compared to no cost of revenues in the same period of 2014. Cost of revenues relates to the costs of our diagnostic service revenues. The costs 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. No tests were completed during the three months ended March 31, 2014.

### *Research and Development Expenses*

Research and development expenses consisted of the following:

		Three Months Ended March 31,		
	2015	2014		Increase (Decrease)
Salaries and staff costs	\$ 799,942	543,791		256,151
Stock-based compensation	289,197	189,635		99,562
Outside services, consultants and lab supplies	921,016	551,250		369,766
Facilities	148,353	130,742		17,611
Travel and scientific conferences	38,238	25,804		12,434
Other	913	1,299		(386)
Total research and development	\$ 2,197,659	\$ 1,442,521		755,138

## Edgar Filing: Trovogene, Inc. - Form 10-Q

### Table of Contents

Research and development expenses increased by \$755,138 to \$2,197,659 for the three months ended March 31, 2015 from \$1,442,521 for the same period in 2014. Our costs have increased as a result of the number of samples processed and validated in connection with our clinical collaborations. 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, 2015 we were a party to over twenty active collaborations or studies, while in the same period of March 31, 2013 we were a party to seven collaborations or studies. As a result of these collaborations, we increased the average number of our internal research and development personnel from ten to fifteen, and purchased additional laboratory equipment, lab supplies and clinical samples. We expect research and development expenses to increase as we enter into additional collaborations.

### *Selling and Marketing Expenses*

Selling and marketing expenses consisted of the following:

	Three Months Ended March 31,		
	2015	2014	Increase/(Decrease)
Salaries and staff costs	\$ 300,131	\$ 318,518	(18,387)
Stock-based compensation	80,488	22,680	57,808
Outside services and consultants	150,680	106,007	44,673
Facilities	58,981	28,068	30,913
Trade shows, conferences and marketing	132,511	65,198	67,313
Travel	33,855	28,877	4,978
Other	38,007	242	37,765
<b>Total sales and marketing</b>	<b>\$ 794,653</b>	<b>\$ 569,590</b>	<b>225,063</b>

Selling and marketing expenses increased by \$225,063 to \$794,653 for the three months ended March 31, 2015 from \$569,590 for the same period in 2014. During the three months ended March 31, 2015 we increased costs primarily as a result of our targeted marketing efforts which included advertising, articles published in electronic newsletters and interviews with key opinion leaders in our field. In addition, we initiated a clinical experience program, where we offered new clinicians three tests for no charge. The costs for the clinical experience program are included in marketing expenses. We expect our selling and marketing expenses to increase as a result of the new headcount additions made to our commercial team in the three months ended March 31, 2015.

### *General and Administrative Expenses*

General and administrative expenses consisted of the following:

	Three Months Ended March 31,		
	2015	2014	Increase/(Decrease)
Salaries and staff costs	\$ 286,743	\$ 175,728	111,015
Board of Directors fees	116,007	65,373	50,634
Stock-based compensation	315,350	347,458	(32,108)

Edgar Filing: Trovogene, Inc. - Form 10-Q

Outside services and consultants	549,479	353,922	195,557
Legal and accounting fees	306,564	203,854	102,710
Facilities and insurance	114,241	59,233	55,008
Travel	85,452	59,264	26,188
Fees, licenses, taxes and other	32,149	93,648	(61,499)
Total general and administrative	\$ 1,805,985	\$ 1,358,480	447,505

General and administrative expenses increased by \$447,505 to \$1,805,985 for the three months ended March 31, 2015, from \$1,358,480 for the same period in 2014. The significant components of the increase were primarily due to continued maintenance of our patent portfolio as well as applications for new patents, additional investor relations activities as we added to our investor base, and additional facilities and insurance costs due to the additional facility space leased and addition of new equipment. We also increased our overall headcount from three to five to support the growth in our research, development and sales and marketing organizations. Stock-based compensation, a non-cash expense, will fluctuate based on the timing and amount of options granted, as well as the fair value of the options at the time of grant or remeasurement. We expect our general and administrative costs to increase to support the growth of our sales and marketing organization and from the additional costs we will incur in the billing and collection of revenues from the sales of our diagnostic tests.

Table of Contents***Change in Fair Value of Derivative Instruments - Warrants***

We have issued securities that are accounted for as derivative liabilities. As of March 31, 2015, the derivative liabilities related to securities issued were revalued to \$4,952,749, resulting in an increase in value of \$1,946,728 from December 31, 2014, based primarily upon the increase in our stock price from \$4.30 at December 31, 2014 to \$6.81 at March 31, 2015 as well as the changes in the expected term and risk free interest rates for the expected term. The increase in value was recorded as a loss 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:

	<b>Three Months Ended March 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>Increase (Decrease)</b>
Net loss attributable to common shareholders	\$ (7,180,441)	\$ (3,199,006)	\$ 3,981,435
Net loss per common share- basic and diluted	\$ (0.33)	\$ (0.17)	\$ 0.16
Weighted average shares-basic and diluted	21,817,710	18,902,782	2,914,928

The \$3,981,435 increase in net loss attributable to common shareholders and \$0.16 increase in net loss per share in 2015 compared to 2014 reflected a slight increase in revenues, an increase in operating expenses, an increase in interest expense, and a loss from the change in fair value in derivative liabilities, compared to the same period in the prior year. Net loss per share in 2015 was also impacted by the increase in weighted average shares outstanding resulting from the sale and issuance of approximately 5.2 million shares of common stock resulting from the sales of stock during the three months ended March 31, 2015, as well as the issuance of approximately 240,000 shares of common stock from the exercise stock options and warrants.

**LIQUIDITY AND CAPITAL RESOURCES**

As of March 31, 2015, we had \$ 43,995,642 in cash and cash equivalents. Net cash used in operating activities for the three months ended March 31, 2015 was \$ 4,732,882, compared to \$2,798,671 for the three months ended March 31, 2014. Our use of cash was primarily a result of the net loss of \$7,174,381 for the three months ended March 31, 2015, adjusted for non-cash items related to stock-based compensation of \$711,741, amortization of debt costs of \$124,713, depreciation and amortization of \$68,519, and the loss from the change in fair value of derivatives of \$1,946,728. The changes in our operating assets and liabilities consisted of lower accounts payable and accrued expenses, an increase in prepaid expenses and other assets, and an increase in accounts receivable. At our current and anticipated level of operating loss, we expect to continue to incur an operating cash outflow for the next several years.

## Edgar Filing: Trovogene, Inc. - Form 10-Q

Investing activities consisted of net purchases for capital equipment that used \$247,097 in cash during the three months ended March 31, 2015, compared to \$118,507 for the same period in 2014.

Net cash provided by financing activities was \$21,681,823 during the three months ended March 31, 2015, compared to net cash used by financing activities of \$48,637 in 2014. Financing activities during the three months ended March 31, 2015 related primarily to the sale of our common stock in an underwritten public offering. Financing activities during the same period of the prior year consisted of repayments of debt.

As of March 31, 2015, and December 31, 2014, we had working capital of \$ 39,167,827 and \$23,231,596, respectively. As of April 30, 2015, our working capital was \$38,054,763.

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. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates, to fund the existing working capital deficit and to continue to fund operations at our current cash expenditure levels. To date, our sources of cash have been primarily limited to the sale of equity securities and debentures. 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.

Table of Contents

*Public Offering and Controlled Equity Offering*

On January 15, 2013 we filed a Form S-3 Registration Statement to offer and sell in one or more offerings, any combination of common stock, preferred stock, warrants, or units having an aggregate initial offering price not exceeding \$150,000,000. The preferred stock, warrants, and units may be convertible or exercisable or exchangeable for common stock or preferred stock or other securities. This form was declared effective on February 4, 2013. In addition, in connection with the Form S-3, we entered into an agreement with Cantor Fitzgerald & Co. ( Agent ) on January 25, 2013 to issue and sell up to \$30,000,000 of shares of common stock through them. As payment for their services, the Agent is entitled to a 3% commission on gross proceeds.

**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, 2014.

**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 instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits.

*Foreign Currency Risk*

We have no operations outside the U.S. and do not hold any foreign currency denominated financial instruments.

*Effects of Inflation*

We do not believe that inflation and changing prices during the three months ended March 31, 2015 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 Chief Executive Officer ( CEO ) and Chief Financial Officer ( CFO ), 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 CFO concluded that our disclosure controls and procedures were effective as of March 31, 2015 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.

**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, 2015 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

**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. None of our directors, officers or affiliates is involved in a proceeding adverse to our business or has a material interest adverse to our business.

**ITEM 1A. RISK FACTORS**

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

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief 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 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, 2015 filed on May 5, 2015, 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.



Table of Contents

**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.

May 5, 2015

By:

/s/ Antonius Schuh  
Antonius Schuh  
Chief Executive Officer

TROVAGENE, INC.

May 5, 2015

By:

/s/ Stephen Zaniboni  
Stephen Zaniboni  
Chief Financial Officer