Trovagene, Inc.
Form 10-Q
November 06, 2014
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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 September 30, 2014

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 000-54556

TROVAGENE, INC.

(Exact Name of small business issuer 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 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 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 October 31, 2014 the issuer had 18,902,783 shares of Common Stock issued and outstanding.

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TROVAGENE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 31,163,559	$ 25,836,937
Accounts receivable	62,370	78,994
Prepaid expenses and other assets	348,018	152,789
Total current assets	31,573,947	26,068,720
Property and equipment, net	841,434	750,565
Other assets	346,902	336,450
Total assets	$ 32,762,283	$ 27,155,735
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 461,769	$ 286,608
Accrued expenses	1,907,930	1,524,092
Current portion of long-term debt	752,734	198,166
Total current liabilities	3,122,433	2,008,866
Long-term debt, less current portion	13,978,818	322,998
Other long-term liability	96,060	
Derivative financial instruments	3,211,216	4,431,871
Total liabilities	20,408,527	6,763,735
Commitments and contingencies (Note 9)		
Stockholders equity		
Preferred stock, $0.001 par value, 20,000,000 shares authorized; 60,600 shares outstanding at September 30, 2014 and December 31, 2013; designated as Series A Convertible Preferred Stock with liquidation preference of $606,000 at September 30, 2014 and December 31, 2013	60	60
Common stock, $0.0001 par value, 150,000,000 shares authorized; 18,902,783 shares issued and outstanding at September 30, 2014 and December 31, 2013	1,890	1,890
Additional paid-in capital	89,054,276	87,433,460
Accumulated deficit	(76,702,470)	(67,043,410)
Total stockholders equity	12,353,756	20,392,000
Total liabilities and stockholders equity	$ 32,762,283	$ 27,155,735

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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Royalty income	$ 57,199	$ 43,756	$ 213,780	$ 211,879
License fees			10,000	
Total revenues	57,199	43,756	223,780	211,879
Costs and expenses:				
Research and development	1,990,251	915,457	4,829,945	2,661,550
Selling and marketing	540,584	330,525	1,699,988	1,156,157
General and administrative	1,466,592	1,875,427	4,135,310	4,235,776
Total operating expenses	3,997,427	3,121,409	10,665,243	8,053,483
Loss from operations	(3,940,228)	(3,077,653)	(10,441,463)	(7,841,604)
Interest income	3,470	44	7,940	44
Interest expense	(389,871)	(6,263)	(454,082)	(6,931)
Other (expense) income, net	(19,255)		24,845	
Change in fair value of derivative instruments warrants	(1,029,333)	(1,317,360)	1,220,655	(2,933,527)
Net loss	(5,375,217)	(4,401,232)	(9,642,105)	(10,782,018)
Preferred stock dividend	(6,060)	(5,360)	(16,955)	(20,630)
Net loss attributable to common stockholders	$ (5,381,277)	$ (4,406,592)	$ (9,659,060)	$ (10,802,648)
Net loss per common share-basic and diluted	$ (0.28)	$ (0.25)	$ (0.51)	$ (0.66)
Weighted average shares outstanding- basic and diluted	18,902,783	17,870,703	18,902,783	16,330,313

See accompanying notes to the unaudited condensed consolidated financial statements.

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TROVAGENE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2014	**2013**
Operating activities		
Net loss	$ (9,642,105)	$ (10,782,018)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net gain on disposal of fixed assets	(24,845)	
Depreciation and amortization	169,599	85,532
Accretion of discount on debt	28,686	
Non-cash interest expense		2,085
Stock based compensation expense	1,384,959	1,856,684
Change in fair value of financial instruments	(1,220,655)	2,933,527
Changes in operating assets and liabilities:		
Increase in other assets	(10,452)	(49,831)
Decrease in accounts receivable	16,624	98,815
Increase in prepaid expenses	(195,229)	(69,352)
Increase in accounts payable,accrued expenses and other long-term liabilities	632,904	462,078
Net cash used in operating activities	(8,860,514)	(5,462,480)
Investing activities:		
Capital expenditures, net	(235,623)	(571,097)
Net cash used in investing activities	(235,623)	(571,097)
Financing activities:		
Proceeds from exercise of warrants		3,599,831
Proceeds of sale of common stock, net of expenses		18,897,388
Borrowings under debt agreement, net of expenses	14,938,723	
Net (repayments) borrowings from equipment line of credit	(515,964)	515,964
Net cash provided by financing activities	14,422,759	23,013,183
Net change in cash and equivalents	5,326,622	16,979,606
Cash and cash equivalents Beginning of period	25,836,937	10,819,781
Cash and cash equivalents End of period	$ 31,163,559	$ 27,799,387
Supplementary disclosure of cash flow activity:		
Cash paid for taxes	$ 2,400	$ 7,650
Cash paid for interest	$ 248,506	$ 3,339
Supplemental disclosure of non-cash investing and financing activities:		
Reclassification of derivative financial instruments to additional paid in capital	$	$ (5,417,871)
Preferred stock dividends accrued	$ 16,955	$ 20,630
Warrants issued in connection with Loan and Security Agreement	$ 235,857	$

See accompanying notes to the unaudited condensed consolidated financial statements.

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TROVAGENE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Business Overview, Basis of Presentation and Liquidity

Business Overview

Trovagene, Inc. (Trovagene or the Company) is focused on developing and commercializing its precision cancer monitoring technology, which can inform oncologists and guide treatment decisions by determining a tumor s mutational status and enabling oncologists to track therapeutic response and resistance over time.

The Company is in the process of expanding the body of clinical evidence supporting its urine-based cell-free DNA mutation tracking platform through collaborations with major cancer treatment centers and integrated healthcare networks. This year, Trovagene expects that the benefits of its precision cancer monitoring technology will become more apparent in terms of its clinical utility and impact on patient outcomes. The Company s intellectual property estate protecting its technology includes methods of extracting, purifying, preparing, and detecting cell-free DNA and RNA mutations in both blood and urine.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Trovagene, 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. Certain items in the comparable prior period s financial statements have been reclassified to conform to the current period s presentation. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements as of December 31, 2013 and 2012 and for each of the three years ended December 31, 2013 included in the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2014. The accompanying condensed consolidated financial statements have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at September 30, 2014, and for all periods presented herein, have been made. The results of operations for the periods ended September 30, 2014 and 2013 are not necessarily indicative of the operating results for the full year.

In June 2014, the Financial Accounting Standards Board (the FASB) issued an accounting standards update that removes the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminate the requirements for development stage entities to: (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and disclose in the first year in which the entity is no longer a development stage entity that in prior

years it had been in the development stage. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2014, with an option for early adoption. The Company elected early adoption, and does not believe the adoption of the standard had a material impact on our financial position, results of operations or related financial statement disclosures.

Liquidity

Trovagene s condensed consolidated financial statements as of September 30, 2014 have been prepared under the assumption that Trovagene will continue as a going concern. The Company s ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate additional revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on current plans the Company will be required to raise additional capital during 2016 to complete the development and commercialization of current product candidates and to continue to fund operations at its current projected cash expenditure levels.

The Company cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that the Company can raise additional funds by issuing equity securities, the Company s stockholders may experience significant dilution. Any

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debt financing, if available, may involve restrictive covenants that impact the Company s ability to conduct its business.

If the Company is unable to raise additional capital when required or on acceptable terms, it may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of its product candidates. The Company may also be required to:

- 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; and

- Relinquish licenses or otherwise dispose of rights to technologies, product candidates or products that the Company would otherwise seek to develop or commercialize themselves, on unfavorable terms.

The Company has approximately $30.0 million of cash and cash equivalents at October 31, 2014.

2. 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 and diluted 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. In a period where there is a net loss position, diluted weighted-average shares are the same as basic weighted-average shares. Shares used in calculating basic and diluted net loss per common share for the nine months ended September 30 exclude as antidilutive the following share equivalents:

	September 30,	
	2014	**2013**
Options to purchase Common Stock	4,233,749	3,894,044
Warrants to purchase Common stock	6,302,286	6,306,582
Series A Convertible Preferred Stock	63,125	63,125
	10,599,160	10,263,751

3. Accounting for Share-Based Payments

Stock Options

ASC Topic 718 *Compensation Stock Compensation* requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. Trovagene accounts for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 *Equity-Based Payment to Non-Employees* whereas the value of the stock compensation is based upon the measurement date as determined at either: a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being marked to market quarterly until the measurement date is determined.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Included in research and development expense	$ 171,150	$ 124,447	$ 526,803	$ 426,656
Included in selling and marketing expense	49,887	14,836	102,556	60,637
Included in general and administrative expense	184,663	829,793	755,600	1,369,391
Total stock-based compensation expense	$ 405,700	$ 969,076	$ 1,384,959	$ 1,856,684

The unrecognized compensation cost related to non-vested stock options outstanding at September 30, 2014 and 2013, net of expected forfeitures, was $ 3,805,661 and $3,170,227, 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 September 30, 2014 was approximately seven years.

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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:

	Nine Months Ended September 30,	
	2014	2013
Risk-free interest rate	1.5-2.1%	0.74 1.48%
Dividend yield	0%	0%
Expected volatility	81-83%	95-100%
Expected term (in years)	4-6 yrs	5 yrs

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

	Total Options	Weighted Average Exercise Price Per Share	Intrinsic Value
Balance outstanding, December 31, 2013	4,287,545	$ 5.18	
Granted	626,870		
Forfeited	(690,666)		
Balance outstanding, September 30, 2014	4,233,749	$ 4.71	$ 3,592,365
Exercisable at September 30, 2014	2,107,069	$ 4.76	$ 2,211,482

The Trovagene Stock Option Plan expired on June 24, 2014. The Trovagene Inc. 2014 Equity Incentive Plan, 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.

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, 2013	6,233,483	$ 3.87	4.5 years
Granted	85,470	$ 3.51	
Forfeited	(16,667)	$ 10.80	
Balance outstanding, September 30, 2014	6,302,286	$ 3.84	3.8 years

4. 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 Trovagene 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. There were no sales of common stock during the nine months ended September 30, 2014.

5. Asset Purchase Agreement

On February 1, 2012, the Company entered into an asset purchase agreement with MultiGen Diagnostics, Inc. The Company determined that the acquired asset did not meet the definition of a business, as defined in ASC 805*, Business Combinations* and was

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accounted for under ASC 350, *Intangibles- Goodwill and Other* . In connection with the acquisition, the Company issued 125,000 shares of restricted common stock to MultiGen. In addition, up to an additional $3.7 million may be paid in a combination of common stock and cash to MultiGen upon the achievement of specific sales and earnings targets. In addition, in connection with the acquisition, the Company entered into a Reagent Supply Agreement dated as of February 1, 2012 pursuant to which MultiGen will supply and deliver reagents to be used in connection with a Clinical Laboratory Improvement Amendment (CLIA) laboratory. The total purchase consideration was determined to be $187,500 which was paid in the Company s common stock and allocated to an indefinite lived intangible asset related to the CLIA license.

6. Derivative Financial Instruments - Warrants

The Company follows the provisions of ASC Topic 815-40, Derivatives and Hedging: Contracts in Entity s Own Equity for its derivative instruments. ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity s own stock, which would qualify as a scope exception under ASC Topic 815-10.

Based upon the Company s analysis of the criteria contained in ASC Topic 815-40, Trovagene has determined that the warrants issued in connection with certain of its debentures must be recorded as derivative liabilities. Accordingly the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company s condensed consolidated statement of operations.

The Company estimates the fair value of the warrants issued in connection with certain of its debentures using the Black-Scholes model in order to determine the associated derivative instrument liability and change in fair value described above. The following range of assumptions was used to determine the fair value of the warrants during the periods indicated:

	Nine Months Ended September 30,	
	2014	2013
Estimated fair value of Trovagene common stock	$ 3.50-5.73	$ 6.26 7.18
Expected warrant term	4.3-4.8 yrs	1 5.8 yrs
Risk-free interest rate	1.6-1.8%	0.03 1.41%
Expected volatility	74-83%	95-100%
Dividend yield	0%	0%

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, 2013	Balance of derivative financial instruments	1,013,961	$ 4,431,871

	liability			
	Change in fair value of warrants during the period recognized as a gain in the condensed consolidated statement of operations			(1,220,655)
September 30, 2014	Balance of derivative financial instruments liability	1,013,961	$	3,211,216

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7. Fair Value Measurements

Fair value of financial instruments

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 September 30, 2014 and December 31, 2013:

	Fair Value Measurements at September 30, 2014			
	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)	$ 30,989,822	$	$	$ 30,989,822
Total Assets	$ 30,989,822	$	$	$ 30,989,822
Liabilities:				
Derivative liabilities related to warrants	$	$	$ 3,211,216	$ 3,211,216
Total Liabilities	$	$	$ 3,211,216	$ 3,211,216

	Fair Value Measurements at December 31, 2013			
	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)	$ 25,703,330	$	$	$ 25,703,330
Total Assets	$ 25,703,330	$	$	$ 25,703,330
Liabilities:				
Derivative liabilities related to warrants		$	$ 4,431,871	$ 4,431,871
Total Liabilities	$	$	$ 4,431,871	$ 4,431,871

(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 nine months ended September 30, 2014:

Description	Balance at December 31, 2013	Unrealized Gain	Balance at September 30, 2014
Derivative liabilities related to Warrants	$ 4,431,871	$ (1,220,655)	$ 3,211,216

The unrealized gain 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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8. 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.

The Company recorded approximately $61,000 in interest expense related to the Equipment Line of Credit from January 1, 2014, until the loan was paid in full in June 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. A portion of the proceeds were used to repay the existing equipment loan. The repayment with the same lender was accounted for as a debt extinguishment under ASC Topic 470-50, *Debt*. The interest rate on the new 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.

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.

Long-term debt and unamortized discount balances are as follows:

Balance at December 31, 2013	$	
Face value of term loan		15,000,000
Debt discount		(297,134)
Accretion of debt discount		28,686
Balance at September 30, 2014	$	14,731,552

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

Year Ending December 31,		
2014	$	
2015		1,898,549
2016		4,790,628
2017		5,140,519
2018		3,170,304
Total future minimum payments		15,000,000
Debt discount, net of accretion		(268,448)
Total minimum principal payments		14,731,552

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The Company recorded approximately $392,817 in interest expense related to the Loan and Security Agreement during the nine months ended September 30, 2014.

9. Commitments and Contingencies

Executive and Consulting Agreements

The Company has contracted with various consultants and third parties, 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 8,300 square feet of office space at a monthly rental rate of approximately $18,300 to $20,000 during the remaining term of the lease, through December 2017. Effective May 14, 2014, the Company entered into the fifth amendment of its lease (the Agreement), which increased the leased space by 4,751 square feet and increased the monthly rent by approximately $10,500 per month, commencing in October 2014.

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 September 30, 2014, the Company has incurred and recorded approximately $244,000 of research and development expenses related to these agreements.

In April 2013, the Company entered into a research and development agreement with PerkinElmer Health Sciences, Inc. (PerkinElmer) pursuant to which the Company will design an assay, based on the Company s urine-based cell-free molecular diagnostic technology, to determine the risk for developing hepatocellular carcinoma. A notice of termination was received in March 2014 terminating the agreement. No further commitments exist from either party. The Company had recognized milestone payments received from PerkinElmer as a reduction in research and development costs as the services were performed. Amounts received in advance of services performed were recorded as accrued liabilities until the services for which the payment had been received were performed. Through the date of termination of the agreement, the Company had received milestone payments of approximately $90,000 and incurred and recorded approximately $90,000 of research and development costs.

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 for an additional year to June 2015.

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 $232,000 for services provided. Through September 30, 2014 the Company has incurred and recorded approximately $6,400 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 September 30, 2014 the Company has incurred and recorded approximately $38,400 of research and development expense related to this agreement.

On May 8, 2014, the Company entered into a Patent Assignment and License Agreement, effective as of April 23, 2014, with GenSignia IP Ltd., a United Kingdom company, pursuant to which the Company assigned all of its miRNA patents, including methods of using miRNA for detection of in vivo cell death and detecting cell-free miRNA in urine and blood. Concurrent with the assignment, GenSignia granted to the Company an exclusive, world-wide, royalty-free, fully paid, perpetual license under the transferred patents in the urine field. Pursuant to the agreement, GenSignia will pay the Company a low single digit royalty on net sales and will pay an aggregate $6.5 million in milestone payments upon the achievement of up to $150 million in net sales. GenSignia shall be responsible for the preparation, filing and maintenance of all patents under the agreement. Antonius Schuh, the Company s CEO and a director, is a director of GenSignia. Dr. Schuh did not participate in any negotiations with respect to the agreement and recused himself from any director vote in connection with the agreement. As of September 30, 2014, the Company had recorded $10,000 in license fee revenue related to the agreement. No costs or expenses have been incurred through September 30, 2014.

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On September 8, 2014, the Company entered into a Sponsored Research Agreement to conduct a validation study to evaluate use of the Company s precision cancer monitoring technology in the management of lung cancer patients. Under the agreement, the Company may pay its collaborator in the study approximately $151,000 for services provided. As of September 30, 2014 the Company has incurred approximately $30,000 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.

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, 2013, filed on March 17, 2014. 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 focused on developing and commercializing our precision cancer monitoring technology, which can inform oncologists; and guide treatment decisions by determining a tumor s mutational status and enabling physicians to track therapeutic response and resistance over time.

We are expanding the body of clinical evidence supporting our urine-based cell-free DNA mutation tracking platform through collaborations with major cancer treatment centers and integrated healthcare networks. We expect that the benefits of our precision cancer monitoring technology will become more apparent in terms of its clinical utility and impact on patient outcomes. Our intellectual property estate protecting our technology includes methods of extracting, purifying, preparing, and detecting cell-free DNA and RNA mutations in urine.

Our accumulated deficit through September 30, 2014 is $76,702,470. To date, we have generated minimal revenues and expect to incur additional losses to perform further research and development activities and commercial expansion. During 2014, we have advanced our business with the following activities:

- On October 27, 2014, we announced the publication of clinical study results in the peer-reviewed medical journal, *Cancer Discovery*, featuring our precision cancer monitoring technology and its ability to non-invasively determine oncogene mutation status and monitor response to *BRAF* inhibitor therapy in patients with histiocytic disease, a malignancy often associated with *BRAF* mutations. These data were subsequently presented at the 30th Annual Histiocyte Society Meeting on October 28, in Toronto, Canada.

- We entered into a sponsored research agreement to evaluate our precision cancer monitoring technology in the management of lung cancer patients.

- We secured $15.0 million in debt financing with Silicon Valley Bank and Oxford Finance to aid in funding our clinical programs,

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commercialization efforts, and continued expansion of our oncogene mutation portfolio for cancer monitoring research.

- We entered into a strategic partnership with the Robert H. Lurie Comprehensive Cancer Center of Northwestern University (Lurie Cancer Center) and the Northwestern Medicine Developmental Therapeutics Institute (NMDTI) to conduct a translational research program designed to assess the utility of our urine-based cell-free oncogene mutation monitoring technology in clinical practice.

- We entered into a clinical collaboration with Dana-Farber Cancer Institute to investigate the utility of quantitative urine-based mutation detection and the ability to monitor tumor mutation burden and treatment response over time in metastatic melanoma patients.

- We introduced our non-invasive cancer monitoring platform with the release of our first multiplexed oncogene mutation assay using next generation sequencing. This allows us to leverage the scalability of our proprietary platform and next generation sequencing to introduce a full line of multiplexed urine-based oncogene mutation assays.

- We entered into a strategic partnership with Catholic Health Initiatives Center for Translational Research to clinically evaluate non-invasive genomic diagnostics to improve cancer care. The partnership seeks to establish clinical and health economic benefits for potential adoption in cancer management strategies.

- Our clinical study results were presented at the American Association for Cancer Research (AACR) Annual Meeting to demonstrate the ability of our molecular diagnostic platform to detect and monitor BRAF V600E mutations in cancer patients. The results were presented by Filip Janku, M.D., Ph.D., of The University of Texas MD Anderson Cancer Center on April 8, 2014.

- We also announced clinical study results in a publication and poster presentation at the 2014 American Society of Clinical Oncology (ASCO) Annual Meeting on June 2, 2014. An abstract published by Filip Janku, M.D., Ph.D. of The University of Texas MD Anderson Cancer Center demonstrated the ability to longitudinally monitor BRAF V600E mutations in urinary cell-free DNA in metastatic cancer patients with our molecular diagnostic technology. Additionally, a poster was presented by Eli Diamond, M.D. of Memorial Sloane Cancer Center demonstrating that our precision cancer monitoring platform was able to determine mutational status and monitor treatment response in patients with histiocytic disease.

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.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of September 30, 2014.

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, 2013, filed with the SEC on March 17, 2014. There have been no changes to our critical accounting policies since December 31, 2013.

RECENT ACCOUNTING PRONOUNCEMENTS

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) (ASU 2014-09). The guidance contains changes to the summary and amendments that create revenue from contracts with customers and other assets, conforms amendments to other topics and subtopics in the codification and status tables, and provides background information and basis for these conclusions. The amendments in the update are effective for annual reporting periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. The Company is considering the impact of adoption of the standard on the condensed consolidated financial statements and have not yet determined the method by which they will adopt the standard in 2017.

In June 2014, the FASB issued ASU No. 2014-12, Compensation Stock Compensation (Topic 718) (ASU 2014-12). The guidance contains changes to the accounting for share-based payments with the terms of an award provide that a performance target could be achieved after the requisition period. The amendments in the update are effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. The amendments should be applied prospectively to all share-based payment awards

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that are granted or modified on or after the effective date and retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. Adoption of the standard is not expected to have a material impact on the condensed consolidated financial statements.

RESULTS OF OPERATIONS

Three Months Ended September 30, 2014 and 2013

Revenues

Our total revenues were $57,199 and $43,756 for the three months ended September 30, 2014 and 2013, respectively. During the three months ended September 30, 2014 and 2013, revenues consisted of royalty income. The increase during the three months ended September 30, 2014 related to royalties received in excess of contractual minimum royalty amounts.

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. Milestone and license fee revenue is difficult to predict and can vary significantly from period to period. In addition, we expect to have revenues from our diagnostics tests in future periods, but as the revenue recognition will be based on cash receipts, the timing of these revenues is also uncertain.

Research and Development Expenses

Research and development expenses consisted of the following:

	Three Months Ended September 30,		
	2014	2013	Increase (Decrease)
Salaries and staff costs	$ 819,212	$ 370,196	449,016
Stock-based compensation	171,150	124,447	46,703
Outside services, consultants and lab supplies	782,309	264,628	517,681
Facilities	177,975	123,178	54,797
Travel and scientific conferences	26,823	18,034	8,789
Other	12,782	14,974	(2,192)
Total research and development	$ 1,990,251	$ 915,457	$ 1,074,794

Research and development expenses increased by $1,074,794 to $1,990,251 for the three months ended September 30, 2014 from $915,457 for the same period in 2013. Substantially all of the increase resulted from the expansion of our research and development efforts to support the clinical collaborations that will validate our tests to detect certain types of cancer in urine samples and monitor responsiveness to therapy and the

status of disease. As a result of the increase in the number of collaborations from five to fifteen, we increased the average number of our internal research and development personnel to eighteen for the three months ended September 30, 2014 from eight during the same period of the prior year. In addition, we purchased additional laboratory equipment, lab supplies and clinical samples as a result in the number of collaborations. We expect research and development expenses to further increase as we enter into additional collaborations.

Selling and Marketing Expenses

Selling and marketing expenses consisted of the following:

	Three Months Ended September 30,		
	2014	**2013**	**Increase/(Decrease)**
Salaries and staff costs	$ 216,056	$ 167,103	48,953
Stock-based compensation	49,887	14,836	35,051
Outside services and consultants	153,290	84,462	68,828
Facilities	31,062	23,806	7,256
Trade shows, conferences and marketing	50,347	35,022	15,325
Travel	31,909	7,678	24,231
Other	8,033	(2,382)	10,415
Total sales and marketing	$ 540,584	$ 330,525	$ 210,059

Selling and marketing expenses increased by $210,059 to $540,854 for the three months ended September 30, 2014 from $330,525 for the same period in 2013. We have increased our average sales and marketing headcount to five in the three months ended September 30, 2014 from three in the same period of 2013, as we expand our efforts to inform the major cancer centers in the United States of our current and future product offerings. We expect these costs to increase as we continue to market and sell our tests.

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General and Administrative Expenses

General and administrative expenses consisted of the following:

	Three Months Ended September 30,		
	2014	**2013**	**Increase/(Decrease)**
Salaries and staff costs	$ 204,238	$ 168,525	35,713
Board of Directors fees	94,354	46,075	48,279
Stock-based compensation	184,663	829,793	(645,130)
Outside services and consultants	408,513	432,633	(24,120)
Legal and accounting fees	428,120	258,270	169,850
Facilities and insurance	74,564	51,646	22,918
Travel	13,834	47,483	(33,649)
Fees, licenses, taxes and other	58,306	41,003	17,303
Total general and administrative	$ 1,466,592	$ 1,875,428	(408,836)

General and administrative expenses decreased by $408,836 to $1,466,592 for the three months ended September 30, 2014, from $1,875,428 for the same period in 2013. The overall decrease resulted primarily from a decrease in stock-based compensation, offset in part by an increase in legal and accounting fees. The three month period ended September 30, 2013 included the stock-based compensation of approximately $500,000 associated with an option grant to one of our Directors for services provided outside of routine Board of Directors activities, while there was no comparable compensation in the three month period ended September 30, 2014. Continued patent filing and maintenance as well as the costs associated with being a publicly traded company, such as additional costs for insurance, NASDAQ fees and Sarbanes-Oxley compliance have added to our general and administrative expenses, in comparison to the same period of the prior year. Stock-based compensation, a non-cash expense, will fluctuate based on the timing and amount of share based awards granted, as well as the fair value of the awards at the time of grant or remeasurement. We expect our general and administrative costs to increase as a result of our accelerated filer status and as we raise more capital.

Interest Expense

Interest expense increased to $389,871 for the three months ended September 30, 2014, from $6,263 for the same period in 2013. The increase resulted from an increase in our average debt outstanding during the three months ended September 30, 2014 compared to the same period of the prior year, as a result of borrowings under Loan and Security Agreement we entered into in June 2014.

Change in Fair Value of Derivative Instruments - Warrants

We have issued securities that are accounted for as derivative liabilities. As of September 30, 2014, the derivative liabilities related to securities issued were revalued to $3,211,216, resulting in a net increase in value of $1,029,333 from June 30, 2014, based primarily upon the increase in our stock price from $3.50 at June 30, 2014 to $4.58 at September 30, 2014 and the changes in the expected term and risk free interest rates for the expected term. The increase in value was recorded as non-operating loss for the three months ended September 30, 2014.

Net Loss

Net loss and per share amounts were as follows:

	Three Months Ended September 30,		
	2014	**2013**	**Increase (Decrease)**
Net loss attributable to common shareholders	$ (5,381,277)	$ (4,406,592)	$ 974,685
Net loss per common share: basic and diluted	$ (0.28)	$ (0.25)	$ (0.03)
Weighted average shares: basic and diluted	18,902,783	17,870,703	1,032,080

The $974,685 increase in net loss attributable to common shareholders and $0.03 increase in net loss per share in 2014 compared to 2013 reflected a slight increase in revenues, an increase in operating expenses, and a decrease in the loss from the change in fair value in derivative liabilities, compared to the same period in the prior year. Net loss per share in 2014 was also impacted by the increase in weighted average shares outstanding resulting from the sale and issuance of approximately 3.4 million shares of common stock resulting from the sales of stock during the third quarter of 2013, as well as the exercise of stock options and warrants from August 1, 2013

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through December 31, 2013.

Nine Months Ended September 30, 2014 and 2013

Revenues

Our total revenues were $223,780 and $211,879 for the nine months ended September 30, 2014 and 2013, respectively. During the nine months ended September 30, 2014, revenues consisted of $10,000 of license fees and $213,780 of royalty income, while revenue in the same period of the prior year was comprised of all royalty income. The $10,000 license fee revenue in the nine months ended September 30, 2014 related to cash received for a license agreement signed in the second quarter of 2014. There was no license fee revenue in the nine months ended September 30, 2013 and no diagnostic revenue in the nine months ended September 30, 2014 and 2013.

We expect our royalty income to fluctuate as the royalties are based on the portion of our partners revenues as well as the timing of when payments are received. Milestone and license fee revenue is difficult to predict and can vary significantly from period to period. In addition, we expect to have revenues from our diagnostics tests in future periods, but as the revenue recognition will be based on cash receipts, the timing of these revenues is also uncertain.

Research and Development Expenses

Research and development expenses consisted of the following:

	Nine Months Ended September 30,		
	2014	2013	Increase
Salaries and staff costs	$ 2,000,125	$ 979,244	$ 1,020,881
Stock-based compensation	526,803	426,656	100,147
Outside services, consultants and lab supplies	1,743,485	848,204	895,281
Facilities	454,591	322,478	132,113
Travel and scientific conferences	71,169	51,952	19,217
Other	33,772	33,017	755
Total research and development	$ 4,829,945	$ 2,661,551	$ 2,168,394

Research and development expenses increased by $2,168,394 to $4,829,945 for the nine months ended September 30, 2014 from $2,661,551 for the same period in 2013. Substantially all of the increase resulted from the expansion of clinical programs to support the collaborations we have entered into that support validation of our tests for detection of certain types of cancer in urine and monitoring the status of cancer after therapeutic intervention. As a result of these collaborations, we increased the average number of our internal research and development personnel from eight to sixteen, 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:

	Nine Months Ended September 30,		
	2014	**2013**	**Increase/(Decrease)**
Salaries and staff costs	$ 818,797	$ 571,560	$ 247,237
Stock-based compensation	102,556	60,637	41,919
Outside services and consultants	369,638	219,791	149,847
Facilities	85,616	69,655	15,961
Trade shows, conferences and marketing	204,263	136,939	67,324
Travel	109,972	63,284	46,688
Other	9,146	34,291	(25,145)
Total sales and marketing	$ 1,699,988	1,156,157	$ 543,831

Selling and marketing expenses increased by $543,831 to $1,699,988 for the nine months ended September 30, 2014 from $1,156,157 for the same period in 2013. We have increased our average sales and marketing headcount to five during the nine months ended September 30, 2014, from three in the same period of the prior year, and also increased costs as we expand our efforts to inform the major cancer centers in the United States of our current and future product offerings. We expect these costs to increase as we continue to market and sell our tests.

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General and Administrative Expenses

General and administrative expenses consisted of the following:

	Nine Months Ended September 30,		
	2014	**2013**	**Increase/(Decrease)**
Salaries and staff costs	$ 599,874	$ 414,342	$ 185,532
Board of Directors fees	242,477	170,930	71,547
Stock-based compensation	755,599	1,369,391	(613,792)
Outside services and consultants	1,055,697	1,016,032	39,665
Legal and accounting fees	954,089	791,795	162,294
Facilities and insurance	195,401	189,340	6,061
Travel	138,026	170,262	(32,236)
Fees, licenses, taxes and other	194,147	113,684	80,463
Total general and administrative	$ 4,135,310	$ 4,235,776	$ (100,466)

General and administrative expenses decreased by $100,466 to $4,135,310 for the nine months ended September 30, 2014, from $4,235,776 for the same period in 2013. The overall decrease resulted primarily from a decrease in stock-based compensation, offset in part by an increase salaries and staff costs, fees paid to the Board of Directors, and legal and accounting fees. The nine month period ended September 30, 2013 included the stock-based compensation of approximately $500,000 associated with an option grant to one of our Directors for services provided outside of routine Board of Directors activities, while there was no comparable compensation in the same period ended September 30, 2014. Our average headcount has increased from two in the nine months ended September 30, 2013 to four in the nine months ended September 30, 2014, in support of the growth of our sales and marketing and research and development functions. Sarbanes-Oxley compliance has also added to our general and administrative expenses in comparison to the same period of the prior year. We expect our general and administrative costs to increase as our overall headcount increases.

Interest Expense

Interest expense increased to $454,082 for the nine months ended September 30, 2014, from $6,931 for the same period in 2013. The increase resulted from an increase in our average debt outstanding during the nine months ended September 30, 2014 compared to the same period of the prior year, primarily as a result of borrowings under the equipment line of credit we established in June 2013 and the Loan and Security Agreement we entered into in June 2014. We expect our interest expense to increase due to an increase in our average debt outstanding.

Change in Fair Value of Derivative Instruments - Warrants

We have issued securities that are accounted for as derivative liabilities. As of September 30, 2014, the derivative liabilities related to securities issued were revalued to $3,211,216 resulting in a net decrease in value of $1,220,655 from December 31, 2013, based primarily upon the change in our stock price from $5.74 at December 31, 2013 to $4.58 at September 30, 2014 and the changes in the expected term, risk free interest rates and volatility for the expected term. The decrease in value was recorded as non-operating gain for the nine months ended September 30, 2014.

Net Loss

Net loss and per share amounts were as follows:

	Nine Months Ended September 30,		
	2014	**2013**	**Increase (Decrease)**
Net loss attributable to common shareholders	$ (9,659,060)	$ (10,802,648)	$ (1,143,588)
Net loss per common share: basic and diluted	$ (0.51)	$ (0.66)	$ (0.15)
Weighted average shares: basic and diluted	18,902,783	16,330,313	2,572,470

The $1,143,588 decrease in net loss attributable to common shareholders and $0.15 decrease in net loss per share in 2014 compared to 2013 reflected a slight increase in revenues, an increase in operating expenses, offset by the gain on the change in fair value

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in derivative liabilities. Net loss per share in 2014 was also impacted by the increase in weighted average shares outstanding resulting from the sale and issuance of approximately 3.4 million shares of common stock resulting from the sales of stock during the third quarter of 2013, and the exercise of stock options and warrants from April 1, 2013 through December 31, 2013.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2014, we had $31,163,559 in cash and cash equivalents. Net cash used in operating activities for the nine months ended September 30, 2014 was $8,860,516, compared to $5,462,480 for the nine months ended September 30, 2013. Our use of cash was primarily a result of the net loss of $9,642,105 for the nine months ended September 30, 2014, adjusted for non-cash items related to stock-based compensation of $1,384,959, depreciation and amortization of $169,599 and the gain from the change in fair value of derivatives of $1,220,655. The changes in our operating assets and liabilities consisted of higher accounts payable and accrued expenses, prepaid expenses and other assets, and a decrease 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.

Investing activities consisted of net purchases for capital equipment that used $235,623 in cash during the nine months ended September 30, 2014, compared to $571,097 for the same period in 2013.

Net cash provided by financing activities was $14,422,759 during the nine months ended September 30, 2014, compared to net cash provided by financing activities of $23,013,183 in 2013. Financing activities during the nine months ended September 30, 2014 related primarily to net borrowings under a Loan and Security Agreement we entered into in June 2014, less the pay-off of an equipment line of credit. Financing activities during the same period of the prior year consisted of $18,897,388 of proceeds received from the sale of common stock, $3,599,831 of proceeds received upon the exercise of warrants, as well as $515,964 of borrowings under an equipment line of credit.

As of September 30, 2014, and December 31, 2013, we had working capital of $28,451,514 and $24,059,854, respectively. As of October 31, 2014, our working capital was $27,298,510.

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 during 2016 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.

Public Offering and Controlled Equity Offering

On January 25, 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

As of September 30, 2014, the material change outside the ordinary course of our business to the contractual obligations we reported in Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Contractual Obligations and Commitments in our annual report on Form 10-K for the year ended December 31, 2013, is disclosed in Note 8. Debt, and relates to the $15.0 million Loan and Security Agreement signed in June 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.

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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 nine months ended September 30, 2014 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 September 30, 2014 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 September 30, 2014 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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, 2013, except for the following:

If the FDA were to begin regulating LDTs, or if we decide to market our products as a medical device rather than a LDT, we could be forced to delay commercialization of our current product candidates, experience significant delays in commercializing any future tests, incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval and/or experience decreased demand for or reimbursement of our test.

We intend to develop products that are considered to be medical devices and are subject to federal regulations including those covering Quality System Regulations (QSR) and Medical Device Reporting (MDR).

The QSR includes requirements related to the methods used in and the facilities and controls used for designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices. Manufacturing facilities undergo FDA inspections to assure compliance with the QS requirements. The quality systems for FDA-regulated products are known as current good manufacturing practices (cGMPs) as described in the Code of Federal Regulations, part 820 (21 CFR part 820). Among the cGMP requirements are those requiring manufacturers to have sufficient appropriate personnel to implement required design controls and other portions of the QSR guidelines.

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Design controls include procedures that describe the product design requirements (design goals) and compare actual output to these requirements, including documented Design Reviews. Required Design History Files (DHFs) for each device will document the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of the QSRs.

QSRs also include stipulation for control of all documents used in design and production, including history of any changes made. Production and process controls include stipulations to ensure products are in fact produced as specified by controlled documents resulting from the controlled design phase, using products and services purchased under controlled purchasing procedures.

Incidents in which a device may have caused or contributed to a death or serious injury must to be reported to FDA under the Medical Device Reporting (MDR) program. In addition, certain malfunctions must also be reported. The MDR regulation is a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner.

We may be required to participate in MDR through two routes. As a manufacturer of products for sale within the United States, we would be required to report to the FDA any deaths, serious injuries and malfunctions, and events requiring remedial action to prevent an unreasonable risk of substantial harm to the public health. Our CLIA lab offering services for sale is already currently required to report suspected medical device related deaths to both the FDA and the relevant manufacturers of products we purchase and use.

Clinical laboratory tests like our current product offerings are regulated in the United States under CLIA as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called LDTs. Most LDTs currently are not subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We expect that, upon the commencement of commercialization, our product candidates will be an LDT and not a diagnostic kit. As a result, we believe that our product candidates should not be subject to regulation under current FDA policies, however there is no assurance that it will not be subject to such regulation in the future. Further, if we decide to market our products as a diagnostic kit rather than a LDT, our products would be subject to FDA regulation as a medical device. The container we expect to provide for collection and transport of tumor samples from a pathology laboratory to our clinical reference laboratory may be a medical device subject to FDA regulation and while we expect that it will be exempt from pre-market review by FDA, there is no certainty in that respect.

At various times since 2006, the FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our tests. In July 2014, the FDA issued a 60 day notice to Congress indicating that the FDA intends to issue draft guidance on the regulation of laboratory developed tests. It is unclear at this time whether the draft guidance will be released officially in September. It is also uncertain whether this draft guidance, if officially released, will be finalized. Legislative proposals addressing oversight of genetic testing and LDTs have been introduced in previous Congresses and we expect that new legislative proposals will be introduced from time to time in the future. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through additional guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests.

If pre-market review is required, our business could be negatively impacted until such review is completed and clearance to market or approval is obtained, and the FDA could require that we stop selling. If pre-market review of our LDTs is required by the FDA, there can be no assurance that our product offerings will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations, such as the Quality

System Regulation and Medical Device Reporting, would increase the cost of conducting our business, and subject us to inspection by the FDA and to the requirements of the FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of our product offerings if we determine that doing so would be appropriate. Some competitors may develop competing tests cleared for marketing by the FDA. There may be a marketing differentiation or perception that an FDA-cleared test is more desirable than our product offerings, and that could discourage adoption and reimbursement of our test.

Should any of the reagents obtained by us from vendors and used in conducting our clinical laboratory service be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

If the FDA decides to regulate our LDTs, it may require that we conduct extensive pre-market clinical studies prior to submitting a regulatory application for commercial sales. If we are required to conduct pre-market clinical studies, whether using retrospectively collected and banked samples or prospectively collected samples, delays in the commencement or completion of clinical studies could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical studies may also ultimately lead to delay or denial of regulatory clearance or approval.

The commencement of clinical studies may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical studies, which might increase the cost of the studies. We will also depend on clinical investigators, medical institutions and contract research organizations to perform the studies properly. If these parties do not successfully carry out their

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contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, FDA requirements or for other reasons, our clinical studies may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our test. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our test, or to become profitable.

ITEM 6. EXHIBITS

Exhibit Number	**Description of Exhibit**
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 September 30, 2014 filed on November 6, 2014, 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.

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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.	
November 6, 2014	By:	/s/ Antonius Schuh Antonius Schuh Chief Executive Officer
	TROVAGENE, INC.	
November 6, 2014	By:	/s/ Stephen Zaniboni Stephen Zaniboni Chief Financial Officer