Trovagene, Inc.
Form 10-Q
November 09, 2015
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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, 2015

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

For the transition period from to

COMMISSION FILE NUMBER 001-35558

TROVAGENE, INC.
(Exact Name of 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 B, San Diego, California 92121
(Address of principal executive offices) (Zip Code)

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

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

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

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

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

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

As of October 30, 2015, the issuer had 29,722,602 shares of Common Stock issued and outstanding.

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TROVAGENE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	9/30/2015	12/31/2014
Assets		
Current assets:		
Cash and cash equivalents	$74,149,797	$27,293,798
Accounts receivable	66,967	56,694
Prepaid expenses and other assets	600,931	369,259
Total current assets	74,817,695	27,719,751
Property and equipment, net	1,842,213	840,387
Other assets	362,946	336,708
Total Assets	$77,022,854	$28,896,846
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,100,073	$747,799
Accrued expenses	2,124,080	1,841,808
Current portion of long-term debt	3,745,198	1,898,548
Total current liabilities	6,969,351	4,488,155
Long-term debt, less current portion	11,519,160	13,053,117
Derivative financial instruments	3,675,926	3,006,021
Total Liabilities	22,164,437	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 September 30, 2015 and December 31, 2014; designated as Series A Convertible Preferred Stock with liquidation preference of $606,000 at September 30, 2015 and December 31, 2014	60	60
Common stock, $0.0001 par value, 150,000,000 shares authorized; 29,722,602 and 18,915,794 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	2,972	1,891
Additional paid-in capital	156,355,718	89,739,511
Accumulated deficit	(101,500,333)	(81,391,909)
Total stockholders' equity	54,858,417	8,349,553
Total liabilities and stockholders' equity	$77,022,854	$28,896,846

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,	
	2015	2014	2015	2014
Royalty income	$51,301	$57,199	$222,931	$213,780
License fees	—	—	—	10,000
Diagnostic service revenue	6,026	—	10,712	—
Total revenues	57,327	57,199	233,643	223,780
Costs and expenses:				
Cost of revenue	173,537	—	429,992	—
Research and development	2,546,533	1,990,251	7,428,349	4,829,945
Selling and marketing	1,798,263	540,584	4,508,766	1,699,988
General and administrative	1,948,546	1,466,592	5,756,047	4,135,310
Total operating expenses	6,466,879	3,997,427	18,123,154	10,665,243
Loss from operations	(6,409,552)	(3,940,228)	(17,889,511)	(10,441,463)
Interest income	17,368	3,470	32,988	7,940
Interest expense	(352,727)	(389,871)	(1,133,068)	(454,082)
Gain (loss) from change in fair value of derivative instruments — warrants	4,017,212	(1,029,333)	(1,105,270)	1,220,655
Other (income) loss, net	(8,130)	(19,255)	4,617	24,845
Net loss and comprehensive loss	(2,735,829)	(5,375,217)	(20,090,244)	(9,642,105)
Preferred stock dividend	(6,060)	(6,060)	(18,180)	(16,955)
Net loss and comprehensive loss attributable to common stockholders	$(2,741,889)	$(5,381,277)	$(20,108,424)	$(9,659,060)
Net loss per common share — basic	$(0.10)	$(0.28)	$(0.80)	$(0.51)
Net loss per common share — diluted	$(0.23)	$(0.28)	$(0.96)	$(0.62)
Weighted average shares outstanding — basic	28,560,211	18,902,783	25,014,966	18,902,783
Weighted average shares outstanding — diluted	29,128,235	18,902,783	25,204,307	19,012,775

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,	
	2015	2014
Operating activities		
Net loss	$(20,090,244)	$(9,642,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net loss (gain) on disposal of fixed assets	4,562	(24,845)
Depreciation and amortization	250,600	169,599
Stock based compensation expense	2,758,847	1,384,959
Amortization of debt costs	253,028	96,060
Accretion of discount on debt	59,665	28,686
Loss (gain) from the change in fair value of derivative instruments - warrants	1,105,270	(1,220,655)
Changes in operating assets and liabilities:		
Increase in other assets	(10,273)	(10,452)
(Increase) decrease in accounts receivable	(231,672)	16,624
Increase in prepaid expenses	(26,238)	(195,229)
Increase in accounts payable and accrued expenses	616,366	536,844
Net cash used in operating activities	(15,310,089)	(8,860,514)
Investing activities:		
Capital expenditures, net	(1,256,988)	(235,623)
Net cash used in investing activities	(1,256,988)	(235,623)
Financing activities:		
Proceeds from sales of common stock, net of expenses	61,215,398	—
Proceeds from exercise of options	818,251	—
Proceeds from exercise of warrants	1,389,427	—
Net borrowings under debt agreements	—	14,938,723
Net repayments from equipment line of credit	—	(515,964)
Net cash provided by financing activities	63,423,076	14,422,759
Net change in cash and equivalents	46,855,999	5,326,622
Cash and cash equivalents—Beginning of period	27,293,798	25,836,937
Cash and cash equivalents—End of period	$74,149,797	$31,163,559
Supplementary disclosure of cash flow activity:		
Cash paid for taxes	$800	$2,400
Cash paid for interest	$795,375	$248,506
Supplemental disclosure of non-cash investing and financing activities:		
Preferred stock dividends accrued	$18,180	$16,955
Warrants issued in connection with Loan and Security Agreement	$—	$235,857
Reclassification of derivative financial instruments to additional paid in capital	$435,365	$—

See accompanying notes to the unaudited condensed consolidated financial statements.

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

1. Organization and Basis of Presentation

Business Organization and Overview

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 changed its name to Trovagene, Inc. In June 2012, the Company's common stock was listed on The NASDAQ Capital Market under the ticker symbol TROV.

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

Basis of Presentation

The accompanying consolidated financial statements of Trovagene, which include its wholly owned subsidiaries Xenomics, Inc., a California corporation 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 GAAP and the rules and regulations of the Securities and Exchange Commission ("SEC") related to a quarterly report on Form 10-Q. Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to those rules and regulations. The unaudited interim condensed consolidated financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the results for the periods presented. All such adjustments are of a normal and recurring nature. The operating results presented in these unaudited interim condensed consolidated financial statements are not necessarily indicative of the results that may be expected for any future periods. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 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 GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

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

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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, might bill third-party payors for testing. The Company is recognizing diagnostic service revenue on the cash collection basis until such time as it is able to properly estimate collections on third party reimbursements.

Derivative Financial Instruments—Warrants

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

The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding the volatility of Trovagene’s common share price, the fair value of the underlying common shares, the remaining life of the warrant, and the risk-free interest rates at each period end. The Company thus uses model-derived valuations where inputs are observable in active markets to determine the fair value and accordingly classifies such warrants in Level 3 per ASC 820, Fair Value Measurements. At September 30, 2015, and December 31, 2014, the fair value of these warrants was $3,675,926 and $3,006,021, respectively, and were included in the derivative financial instruments liability on the balance sheet.

Net Loss Per Share

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

only included when their effect is dilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Numerator: Net loss attributable to common shareholders	$(2,741,889)	$(5,381,277)	$(20,108,424)	$(9,659,060)
Adjustment for change in fair value of derivative instruments - warrants	(4,017,212)	—	(4,017,212)	(2,217,142)
Net loss used for diluted loss per share	$(6,759,101)	$(5,381,277)	$(24,125,636)	$(11,876,202)
Denominator for basic and diluted net loss per share:				
Weighted average shares used to compute basic loss per share	28,560,211	18,902,783	25,014,966	18,902,783
Adjustments to reflect assumed exercise of warrants	568,024	—	189,341	109,992
Weighted average shares used to compute diluted net loss per share	29,128,235	18,902,783	25,204,307	19,012,775
Net loss per share attributable to common stockholders:				
Basic	$(0.10)	$(0.28)	$(0.80)	$(0.51)
Diluted	$(0.23)	$(0.28)	$(0.96)	$(0.62)

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

	September 30,	
	2015	2014
Options to purchase Common Stock	6,514,130	4,233,749
Warrants to purchase Common Stock	4,565,947	5,288,325
Series A Convertible Preferred Stock	63,125	63,125
	11,143,202	9,585,199

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.

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

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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 September 30, 2015 and December 31, 2014:

	Fair Value Measurements at September 30, 2015			
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market fund (1)	$73,493,510		$—	$73,493,510
Total Assets	$73,493,510	$—	$—	$73,493,510
Liabilities:				
Derivative liabilities related to warrants	$—	$—	$3,675,926	$3,675,926
Total Liabilities	$—	$—	$3,675,926	$3,675,926

	Fair Value Measurements at December 31, 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)	$27,123,587	$—	$—	$27,123,587
Total Assets	$27,123,587	$—	$—	$27,123,587
Liabilities:				
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.

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, 2015:

Description	Balance at December 31, 2014	Fair Value of Warrants Reclassified to Additional Paid in Capital	Unrealized Loss	Balance at September 30, 2015
Derivative liabilities related to Warrants	3,006,021	(435,365)	1,105,270	3,675,926

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

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4. Property and Equipment

Property and equipment consist of the following:

	As of September 30, 2015	As of December 31, 2014
Furniture and office equipment	$868,708	$365,955
Leasehold Improvements	39,401	39,401
Laboratory equipment	1,666,970	968,901
	2,575,079	1,374,257
Less—accumulated depreciation and amortization	(732,866)	(533,870)
Property and equipment, net	$1,842,213	$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.

The Company recorded approximately $61,000 in interest expense related to the Equipment Line of Credit from January 1, 2014, until 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 ("Agreement") under which the lenders provided the Company a term loan, which was funded at closing. The interest rate is 7.07% per annum. Under the Agreement, the Company makes 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. Included in the Agreement was a provision to extend the interest only payment to February 1, 2016 upon the Company's receipt of unrestricted net cash proceeds from the sale of equity securities of not less than $30 million by June 30, 2015. In June 2015, the Company entered into an amendment to the Agreement ("Amendment"), which reduced the amount of unrestricted net cash proceeds to not less than $21 million from the sale of equity securities to qualify for an interest extension. The Company met the conditions in the Amendment related to the interest extension, as a result, the interest only payments that were to expire on August 1, 2015 have been extended for six months to February 1, 2016, when both interest and principal payments will commence. The loan is secured by a security interest in all of the Company's assets except intellectual property, which is subject to a negative pledge. In connection with the loan, the lenders received a warrant to purchase an aggregate 85,470 shares of the Company's common stock at an exercise price of $3.51 per share exercisable for ten years from the date of issuance. The original value of the warrants, totaling $235,857, was recorded as debt discount and additional paid-in capital as the warrants were equity classified. As of September 30, 2015, a warrant to purchase 42,735 shares of common stock remains outstanding.

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

The Company is also subject to certain affirmative and negative covenants under the Agreement, including limitations on its ability to: undergo certain change of control events; convey, sell, lease, license, transfer or otherwise dispose of any equipment financed by loans under the loan agreement; create, incur, assume, guarantee or be liable with respect to indebtedness, subject to certain exceptions; grant liens on any equipment financed under the loan agreement; and make or permit any payment on specified subordinated debt. In addition, under the Agreement, subject to certain exceptions, the

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Company is required to maintain with the lender its primary operating, other deposit and securities accounts. Furthermore, under the amendment to the Agreement, the Company is required to be in compliance with healthcare laws and regulations and terms and conditions of healthcare permits. The Company was in compliance with all covenants as of September 30, 2015.

As of September 30, 2015, amounts due under the Agreement include $3,745,198 in current liabilities and $11,519,160 in long-term liabilities. The Company recorded $1,133,068 in interest expense related to the Agreement during the nine months ended September 30, 2015.

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

September 30,	
2016	$3,745,198
2017	5,958,379
2018	5,296,423
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, Trovagene determined that certain warrants issued in connection with the execution of certain equity financings must be recorded as derivative liabilities. In accordance with ASC Topic 815-40, the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant change in fair value is being recorded in the Company's statement of operations. The Company estimates the fair value of these warrants using the Black-Scholes option pricing model.

The 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:

	Nine Months Ended September 30,	
	2015	2014
Estimated fair value of Trovagene common stock	5.69-10.15	3.50-5.73
Expected warrant term	3.3-3.8 years	4.3-4.8 years
Risk-free interest rate	0.89-1.01%	1.62-1.78%
Expected volatility	75-77%	74-83%
Dividend yield	0 %	0 %

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

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

Date	Description	Warrants	Derivative Instrument Liability

December 31, 2014	Balance of derivative financial instruments liability	1,013,961	$3,006,021
	Exercised warrants	(46,666)	(435,365)
	Change in fair value of warrants during the period recognized as a loss in the condensed consolidated statement of operations	—	1,105,270
September 30, 2015	Balance of derivative financial instruments liability	967,295	$3,675,926

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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 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 the Agent. As payment for its services, the Agent is entitled to a 3% commission on gross proceeds.

During the nine months ended September 30, 2015, the Company issued a total of 10,806,808 shares of Common Stock. The Company received gross proceeds of approximately $63.2 million from the sale of 9,711,110 shares of its common stock through an underwritten public offerings in February and July 2015. The Company also received gross proceeds of approximately $2.8 million from the sale of 285,421 shares of its common stock at a weighted average price of $9.66 under the agreement with the Agent. In addition, 250,166 shares were issued upon exercise of options for a weighted average price of $3.27, 282,975 shares were issued upon exercise of warrants for a weighted average price of $4.91, and 277,136 shares were issued upon net exercise of 449,403 warrants at a weighted average exercise price of $3.05.

Stock Options

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,	
	2015	2014	2015	2014
Included in research and development expense	$342,122	$171,150	$1,054,443	$526,803
Included in cost of revenue	7,518	—	22,468	—
Included in selling and marketing expense	225,892	49,887	480,006	102,556
Included in general and administrative expense	348,127	184,663	1,201,929	755,600
Total stock-based compensation expense	$923,659	$405,700	$2,758,846	$1,384,959

The unrecognized compensation cost related to non-vested stock options outstanding at September 30, 2015 and 2014, net of expected forfeitures, was $10,308,131 and $3,805,661, 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, 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 weighted average assumptions during the following periods indicated:

	Nine Months Ended September 30,			
	2015		2014	
Risk-free interest rate	1.77	%	1.83	%
Dividend yield	0	%	0	%
Expected volatility	76	%	82	%
Expected term	6.1 years		5.6 years	

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

	Total Options	Weighted Average Exercise Price Per Share	Intrinsic Value
Balance outstanding, December 31, 2014	4,913,472	$4.66	$2,808,083
Granted	2,174,000	7.54	
Exercised	(250,166)	3.27	
Canceled / Forfeited	(212,175)	4.56	
Expired	(111,001)	14.42	
Balance outstanding, September 30, 2015	6,514,130	5.51	6,732,205
Exercisable at September 30, 2015	2,425,605	4.41	4,211,758

The Trovagene Inc. 2014 Equity Incentive Plan (the "2014 EIP") authorizing up to 2,500,000 shares of common stock for issuance under the Plan was approved by the Board of Directors in June 2014 and approved by the Shareholders at the September 17, 2014 Annual Shareholders' Meeting. An additional 2,500,000 shares of common stock for issuance was authorized by the Board of Directors in March 2015 and approved by the Shareholders at the June 10, 2015 Annual Shareholders' Meeting. As of September 30, 2015 there were 1,813,332 shares available for issuance under the 2014 EIP. The Company will hold a special meeting of stockholders on December 9, 2015 to consider and act upon a proposal to approve an amendment to the 2014 EIP to increase the number of shares issuable to 7,500,000 shares from 5,000,000 shares.

Warrants

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

	Total Warrants	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2014	6,265,620	$3.85	3.57
Exercised	(732,378)	3.77	
Balance outstanding, September 30, 2015	5,533,242	3.86	2.79

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, CFO and Chief Commercial Officer ("CCO") provide for severance payments. The executive agreement with the CEO also provides for a bonus payment in cash or stock upon the earlier of meeting certain trading volumes and market price of Trovagene's common stock for a minimum period of ninety days or in the event of a change in control where the Company's per share enterprise value equal or exceeds $7.50. If the market price and volume target is realized, the bonus is approximately $3.5 million. If a change of control occurs at the targeted enterprise values, the bonus is equal to 4% of the enterprise value.

Lease Agreement

The Company currently leases approximately 13,000 square feet of office and laboratory space at a monthly rental rate of approximately $30,000. On June 11, 2015, the Company entered into an amendment to the lease agreement which will expand the square footage to approximately 22,600 square feet at a monthly rental rate of approximately $60,000. The amended lease will expire on December 31, 2021. The amended monthly rental rate will be effective when the Company commences business operations in the expanded premises, expected to occur in the first quarter of 2016.

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Research and Development Agreements

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. Included in research and development expense, the Company has recorded approximately $1.1million for the nine months ended September 30, 2015 relating to services provided by the collaborators in connection with these agreements.

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

Contingencies

During the Company's internal review process, contingencies were identified regarding various federal and state tax exposures related to issues with respect to certain executive compensation. The settlement of such contingencies may be potentially material to the Company. The Company accrues a liability when it believes that it is both probable that a liability has been incurred and that it can reasonably estimate the amount of the loss. The Company reviews the accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. The Company has not recorded any accrued liabilities related to the potential federal and state tax exposure during the periods presented. To the extent new information is obtained and the Company's views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in the Company's accrued liabilities would be recorded in the period in which such determination is made.

9. Related Party Transactions

In January 2015, the Company entered into a one year consulting agreement with Thomas Adams, Ph.D., our Chairman of the Board, pursuant to which Dr. Adams will provide consulting services in connection with applying the Company’s technology in the field of infectious disease with the first application be to detection of JC virus mutants in the presence of wild type in human urine as a prognostic indicator of the development of PML disease. Under the agreement, the Company has committed to pay $9,500 per month for the services performed by Dr. Adams. Through the nine months ended September 30, 2015, the Company has incurred and recorded $85,500 of consulting fees related to the agreement.

In September 2015, the Company entered into a research agreement with University of Turin (“University”) to collaborate on a program of research to develop, optimize and test molecular profiling tools for plasma and urine ctDNA in cancer. Dr. Alberto Bardelli, the Principal Investigator of the University who oversees this research program is also a member of the Scientific Advisory Board of the Company. Under the agreement, the Company has committed to pay up to $529,000 for the services performed by the University. In addition, the Company may pay royalties to the University on revenue generated by the Company from the commercialization of any tools developed during the collaboration. As of September 30, 2015, the Company has incurred and recorded approximately $48,000 of research and development expenses related to the agreement. No royalty expense has been incurred as of September 30, 2015.

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, 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

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possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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

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

Overview

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

We are leveraging our proprietary molecular diagnostic technology for the detection of cell-free DNA originating from diseased cell death and that can be isolated and detected from urine, blood, and tissue samples to improve disease management.
These genetic materials are also collectively referred to as "cell-free nucleic acids", which result when cells in the body die and release their DNA contents into the bloodstream. The circulating fragments of genetic material are eventually filtered through the kidneys and therefore, can be detected and measured in urine. Cell-free nucleic acids can be used as genetic markers of disease. As such, the contents of urine or blood samples represent systemic liquid biopsies that can allow for simple, non-invasive or minimally-invasive sample collection methods. Circulating tumor DNA is a subtype of cell-free DNA, and represents the mutant cell-free DNA that we use to detect and monitor cancer.

Our fundamental ctDNA diagnostic platform, also known as our Precision Cancer Monitoring^{SM}, ("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 September 30, 2015, our intellectual property portfolio consists of over 88 issued patents worldwide and over 59 pending patent applications globally. Our patent estate includes intellectual property for the detection of cell-free nucleic acids that pass through the kidney into the urine, as well as their application in specific disease areas, including oncology, infectious disease, transplantation, and prenatal genetics.

We believe that our proprietary PCM platform is uniquely positioned to address a high unmet clinical need in field of oncology. Our PCM platform is designed to offer improved cancer monitoring by tracking and analyzing levels of

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

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

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

Our accumulated deficit through September 30, 2015 is $101,500,333. To date, we have generated minimal revenues and expect to incur additional losses to perform further research and development activities and expand commercial operations. During 2015, we have advanced our business with the following activities:

- We formed the Trovagene Research Institute in Europe with Alberto Bardelli, Ph.D., an internationally recognized leader in cell-free DNA cancer research, and currently affiliated with the Department of Oncology, Torino Medical School and the Candiolo Cancer Institute in Italy. We appointed Bardelli as the Scientific Director and transferred core technologies from University of Torino. Trovagene Research Institute intends to improve cancer care through advanced genomic solutions with the mission of accelerating adoption of our PCM platform in translational research and clinical applications.

- 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. In that study, our urinary ctDNA assay identified 100% of tissue biopsy confirmed EGFR T790M mutations (n=10) in metastatic lung cancer patients. Our assay also detected T790M mutations in three subjects that Dr. Husain speculated may have been tissue biopsy false negatives. In addition, data from the study suggest that our assay may be capable of detecting cancer progression earlier than standard imaging and may be useful in determining patient response to novel EGFR T790M inhibitors.

- Clinical study results from a second large-scale clinical trial for our urine-based HPV test were presented by Adriana Lorenzi, a research fellow at the Institute of Education and Research and Molecular Oncology Research Center, Barretos Cancer Hospital - Pio XII Foundation, Barretos, Brazil at the 30th International Papillomavirus Conference. In the trial, urine samples collected from women prior to treatment of cervical pre-cancer lesions (referral population) were tested with Trovagene's HPV HR Test, and results were compared to Roche's cobas® HPV Test results from cervical samples. The trial results were consistent with previously reported Predictors 4 data, which demonstrated that sensitivity with Trovagene's HPV HR Test for the detection of cervical intraepithelial neoplasia Grade Two or higher

("CIN2+") and Grade Three or higher ("CIN3+") were comparable to other established cervical screening tests. In the Brazilian cohort, 271 cases of CIN2+ and 202 cases of CIN3+ disease were tested.

- Clinical study results for our PCM platform were presented by Julia Johansen, M.D. at Herlev Hospital, Copenhagen, and Hatim Husain, M.D., from the University of California, San Diego Moores Cancer Center at the European Cancer Congress. Results demonstrated that quantitative detection and monitoring of ctDNA and driver mutations can be used to rapidly detect treatment response

- We completed an underwritten public offering of 4,600,000 shares of common stock with net proceeds of approximately $37.4 million in July 2015.

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- We entered into a clinical collaboration with Memorial Sloan Kettering Cancer Center to monitor response to immunotherapy in melanoma patients using our PCM platform.

- We launched our "Yellow Is The New Red" marketing campaign for our PCM service at the 2015 American Society of Clinical Oncology Annual Meeting. The campaign is centered on our Clinical Experience Program, in which qualified oncologists can gain hands on clinical experience with the Company's proprietary urinary liquid biopsy tests.

- We completed an underwritten public offering of 5,111,110 shares of common stock with net proceeds of approximately $21.3 million in February 2015.

- 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 potential 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 may allow physicians to determine mutational status, monitor treatment response, and use genomics to aid in predicting patient prognosis.

- 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 potential clinical utilities and advantages of our PCM platform. Our 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 2015 Congress. Based on our analysis of more than 500 samples, the results showed high sensitivity (>90%) for our non-invasive, urine-based HPV assay for the detection of high-risk human papillomavirus ("HPV") types and cervical intraepithelial neoplasia ("CIN") Grade 2 or higher lesions.

- Clinical data from four studies utilizing our PCM platform were presented at the 2015 American Society of Clinical Oncology Annual Meeting in Chicago, IL. Results demonstrated that our PCM technology offers advantages over tissue biopsy and demonstrates the ability to monitor tumor dynamics in lung, pancreatic, and colon cancers.

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

expenses, and competing technologies being developed by organizations with significantly greater resources.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of September 30, 2015.

Critical Accounting Policies

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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 September 30, 2015 and 2014

Revenues

Our total revenues were $57,327 and $57,199 for the three months ended September 30, 2015 and 2014, respectively. The components of our revenues were as follows:

	Three Months Ended September 30,		
	2015	2014	Increase (Decrease)
Royalty income	$51,301	$57,199	$(5,898)
Diagnostic service revenue	6,026	—	6,026
Total revenues	$57,327	$57,199	$128

The $5,898 decrease in royalty income related primarily to lower receipts of payments in excess of minimum royalties in comparison to the same period of the prior year. Diagnostic service revenue is recognized when payment is received for the test results. There was no diagnostic service revenue for the three months ended September 30, 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 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 $173,537 for the three months ended September 30, 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 September 30, 2014.

Research and Development Expenses

Research and development expenses consisted of the following:

	Three Months Ended September 30,		
	2015	2014	Increase (Decrease)
Salaries and staff costs	$1,037,831	$819,212	$218,619
Stock-based compensation	342,122	171,150	170,972
Outside services, consultants and lab supplies	901,662	782,309	119,353

Facilities	193,926	177,975	15,951
Travel and scientific conferences	52,684	26,823	25,861
Other	18,308	12,782	5,526
Total research and development	$2,546,533	$1,990,251	$556,282

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Research and development expenses increased by $556,282 to $2,546,533 for the three months ended September 30, 2015 from $1,990,251 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 September 30, 2015 we were a party to twenty-three active collaborations or studies, while in the same period of September 30, 2014 we were a party to fifteen collaborations or studies. As a result of these collaborations, we increased the average number of our internal research and development personnel from eighteen to twenty-six, 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 September 30,		
	2015	2014	Increase/(Decrease)
Salaries and staff costs	$681,421	$216,056	$465,365
Stock-based compensation	225,892	49,887	176,005
Outside services and consultants	218,582	153,290	65,292
Facilities	70,665	31,062	39,603
Trade shows, conferences and marketing	432,123	50,347	381,776
Travel	157,163	31,909	125,254
Other	12,417	8,033	4,384
Total sales and marketing	$1,798,263	$540,584	$1,257,679

Selling and marketing expenses increased by $1,257,679 to $1,798,263 for the three months ended September 30, 2015 from $540,584 for the same period in 2014. During the three months ended September 30, 2015 we increased the number of our field sales, customer support and marketing personnel, bringing our average headcount to fourteen from five in the same period of the prior year. These additions to our commercial team support our clinical experience program, where we offer new clinicians a series of tests for no charge. The costs of these tests are included in marketing expenses. We expect our selling and marketing expenses to further increase as we hire additional commercial team members.

General and Administrative Expenses

General and administrative expenses consisted of the following:

	Three Months Ended September 30,		
	2015	2014	Increase/(Decrease)
Personnel and outside services costs	$879,722	$612,751	$266,971
Board of Directors' fees	108,612	94,354	14,258
Stock-based compensation	348,127	184,663	163,464
Legal and accounting fees	286,312	428,120	(141,808)
Facilities and insurance	152,714	74,564	78,150
Travel	97,106	13,834	83,272
Fees, licenses, taxes and other	75,953	58,306	17,647
Total general and administrative	$1,948,546	$1,466,592	$481,954

General and administrative expenses increased by $481,954 to $1,948,546 for the three months ended September 30, 2015, from $1,466,592 for the same period in 2014. The significant components of the increase were primarily due to the increase of personnel and outside services costs and stock-based compensation, partially offset by a decrease in legal and accounting fees. The increase of personnel and outside services cost is primarily due to an increase in general and administrative employees, an increase in investor relations activities as our investor base has grown, and increased services related to information technology and human resources to support our overall headcount growth. Stock-based compensation, a

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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 as our commercial operations and research and development teams grow and from the additional costs we will incur in the billing and collection of revenues from the sales of our diagnostic tests.

Change in Fair Value of Derivative Instruments - Warrants

We have issued securities that are accounted for as derivative liabilities. As of September 30, 2015, the derivative liabilities related to securities issued were revalued to $3,675,926, resulting in an decrease in value of $4,017,212 from June 30, 2015, based primarily upon the decrease in our stock price from $10.51 at June 30, 2015 to $5.69 at September 30, 2015 as well as the changes in the expected term and risk free interest rates for the expected term. The decrease in value was recorded as a gain from the change in fair value of derivative liabilities in the condensed consolidated statement of operations.

Net Loss

Net loss and per share amounts were as follows:

	Three Months Ended September 30,		
	2015	2014	Increase (Decrease)
Net loss attributable to common shareholders	$(2,741,889)	$(5,381,277)	$(2,639,388)
Net loss per common share — basic	$(0.10)	$(0.28)	$(0.18)
Net loss per common share — diluted	$(0.23)	$(0.28)	$(0.05)
Weighted average shares outstanding — basic	28,560,211	18,902,783	9,657,428
Weighted average shares outstanding — diluted	29,128,235	18,902,783	10,225,452

The $2,639,388 decrease in net loss attributable to common shareholders and $0.18 decrease in basic net loss per share in 2015 compared to 2014 was primarily the result of the gain from the change in fair value in derivative liabilities, offset by an increase in operating expenses, compared to the same period in the prior year. Basic net loss per share in 2015 was also impacted by the increase in basic weighted average shares outstanding resulting from the sale and issuance of approximately 10.0 million shares of common stock through underwritten public offerings and controlled equity offering through our Agent, as well as the issuance of approximately 823,000 shares of common stock from the exercise of stock options and warrants.

Nine Months Ended September 30, 2015 and 2014

Revenues

Our total revenues were $233,643 and $223,780 for the nine months ended September 30, 2015 and 2014, respectively. The components of our revenues were as follows:

	Nine Months Ended September 30,		
	2015	2014	Increase (Decrease)
Royalty income	$222,931	$213,780	$9,151
License fees	—	10,000	(10,000)
Diagnostic service revenue	10,712	—	10,712
Total revenues	$233,643	$223,780	$9,863

The $9,151 increase in royalty income related primarily to receipts of payments in excess of minimum royalties. The $10,000 license fee earned during nine months ended September 30, 2014 was related to a licensing agreement signed in the second quarter of 2014. There were no license fees earned during the nine months ended September 30, 2015. Diagnostic service revenue is recognized when payment is received for the test results. There was no diagnostic service revenue for the nine months ended September 30, 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. Milestone and license fee revenue is

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difficult to predict and can vary significantly from period to period. In addition, we expect our diagnostic service revenue to increase in future periods, but as the revenue recognition is based on cash receipts, the timing of these revenues is also uncertain.

Cost of Revenues

Our total cost of revenues was $429,992 for the nine months ended September 30, 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 nine months ended September 30, 2014.

Research and Development Expenses

Research and development expenses consisted of the following:

	Nine Months Ended September 30,		
	2015	2014	Increase (Decrease)
Salaries and staff costs	$2,679,951	$2,000,125	$679,826
Stock-based compensation	1,054,443	526,803	527,640
Outside services, consultants and lab supplies	2,955,738	1,743,485	1,212,253
Facilities	552,259	454,591	97,668
Travel and scientific conferences	148,766	71,169	77,597
Other	37,192	33,772	3,420
Total research and development	$7,428,349	$4,829,945	$2,598,404

Research and development expenses increased by $2,598,404 to $7,428,349 for the nine months ended September 30, 2015 from $4,829,945 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 nine months ended September 30, 2015 we were a party to twenty-four active collaborations or studies, while in the same period of September 30, 2014 we were a party to fifteen collaborations or studies. As a result of these collaborations, we increased the average number of our internal research and development personnel from sixteen to twenty, 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,		
	2015	2014	Increase/(Decrease)
Salaries and staff costs	$1,758,789	$818,797	$939,992
Stock-based compensation	480,006	102,556	377,450
Outside services and consultants	654,512	369,638	284,874
Facilities	210,153	85,616	124,537
Trade shows, conferences and marketing	1,005,859	204,263	801,596

Travel	330,399	109,972	220,427
Other	69,048	9,146	59,902
Total sales and marketing	$4,508,766	$1,699,988	$2,808,778

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Selling and marketing expenses increased by $2,808,778 to $4,508,766 for the nine months ended September 30, 2015 from $1,699,988 for the same period in 2014. During the nine months ended September 30, 2015 we increased the number of our field sales, customer support and marketing personnel, bringing our average headcount to eleven from five in the same period of the prior year. These additions to our commercial team support our clinical experience program, where we offer new clinicians a series of tests for no charge, and the costs for the completion of these tests are included in marketing expenses.

General and Administrative Expenses

General and administrative expenses consisted of the following:

	Nine Months Ended September 30,		
	2015	2014	Increase/(Decrease)
Personnel and outside services costs	$2,582,108	$1,655,571	$926,537
Board of Directors' fees	339,823	242,477	97,346
Stock-based compensation	1,201,929	755,599	446,330
Legal and accounting fees	855,101	954,089	(98,988)
Facilities and insurance	366,109	195,401	170,708
Travel	206,741	138,026	68,715
Fees, licenses, taxes and other	204,236	194,147	10,089
Total general and administrative	$5,756,047	$4,135,310	$1,620,737

General and administrative expenses increased by $1,620,737 to $5,756,047 for the nine months ended September 30, 2015, from $4,135,310 for the same period in 2014. The significant components of the increase were primarily due to the increase of personnel and outside services costs, stock-based compensation and facilities and insurance. The increase of personnel and outside services costs is due to an increase in average headcount from four to six to support the growth in our research, development and sales and marketing organizations, an increase in investor relations activities as our investor base has grown, and increased services related to information technology and human resources to support our overall headcount growth. 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 and research and development operations and from the additional costs we will incur in the billing and collection of revenues from the sales of our diagnostic tests.

Change in Fair Value of Derivative Instruments - Warrants

We have issued securities that are accounted for as derivative liabilities. As of September 30, 2015, the derivative liabilities related to securities issued were revalued to $3,675,926, resulting in an increase in value of $669,905 from December 31, 2014, based primarily upon the increase in our stock price from $4.30 at December 31, 2014 to $5.69 at September 30, 2015 as well as the changes in the expected term and risk free interest rates for the expected term, offset by fair value of warrants reclassified from the liability to additional paid in capital upon exercise of warrants. 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.

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Net Loss

Net loss and per share amounts were as follows:

	Nine Months Ended September 30,		
	2015	2014	Increase (Decrease)
Net loss attributable to common shareholders	$(20,108,424)	$(9,659,060)	$10,449,364
Net loss per common share — basic	$(0.80)	$(0.51)	$0.29
Net loss per common share — diluted	$(0.96)	$(0.62)	$0.34
Weighted average shares outstanding — basic	25,014,966	18,902,783	6,112,183
Weighted average shares outstanding — diluted	25,204,307	19,012,775	6,191,532

The $10,449,364 increase in net loss attributable to common shareholders and $0.29 increase in basic net loss per share in 2015 compared to 2014 reflected a slight increase in revenues, offset by an increase in operating expenses, interest expense, and the loss from the change in fair value in derivative liabilities, compared to the same period in the prior year. Basic net loss per share in 2015 was also impacted by the increase in basic weighted average shares outstanding resulting from the sale and issuance of approximately 10.0 million shares of common stock through underwritten public offerings and controlled equity offering through our Agent, as well as the issuance of approximately 823,000 shares of common stock from the exercise of stock options and warrants.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2015, we had $74,149,797 in cash and cash equivalents. Net cash used in operating activities for the nine months ended September 30, 2015 was $15,310,089, compared to $8,860,514 for the nine months ended September 30, 2014. Our use of cash was primarily a result of the net loss of $20,090,244 for the nine months ended September 30, 2015, adjusted for non-cash items related to stock-based compensation of $2,758,847, amortization of debt costs of $253,028, accretion of discount on debt of $59,665, depreciation and amortization of $250,600, and the loss from the change in fair value of derivatives of $1,105,270. The changes in our operating assets and liabilities consisted of higher 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.

Investing activities consisted of net purchases for capital equipment that used $1,256,988 in cash during the nine months ended September 30, 2015, compared to $235,623 for the same period in 2014.

Net cash provided by financing activities was $63,423,076 during the nine months ended September 30, 2015, compared to $14,422,759 in 2014. Financing activities during the nine months ended September 30, 2015 related primarily to the sale of our common stock in underwritten public offerings. Financing activities during the same period of the prior year consisted of net borrowings under debt agreements.

As of September 30, 2015, and December 31, 2014, we had working capital of $67,848,344 and $23,231,596, respectively. As of October 31, 2015, our working capital was $65,945,723.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of our research and development programs and ramp up of our sales and marketing function. To date, our sources of cash have been primarily limited to the sale of equity securities and debentures and a venture capital loan. 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.

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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 the Agent. 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 nine months ended September 30, 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 CEO and 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, 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.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives as specified above. Management does not expect, however, that our disclosure controls and procedures will prevent or detect all

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errors and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the three months ended September 30, 2015 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any pending legal proceeding, nor is our property the subject of a pending legal proceeding, that is not in the ordinary course of business or otherwise material to the financial condition of our business. 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

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

We are a development stage company and we may never earn a profit.

We are a development stage company and have incurred losses since we were formed. As of September 30, 2015 and December 31, 2014, we have an accumulated total deficit of approximately $101.5 million and $81.4 million, respectively. For the nine months ended September 30, 2015 and the fiscal year ended December 31, 2014, we had a net loss and comprehensive loss attributable to common stockholders of approximately $20.1 million and $14.3 million, respectively. To date, we have experienced negative cash flow from development of our cell-free molecular diagnostic technology. Revenue generated from operations is largely due to licensing, milestone and royalty income. We also generated an immaterial amount of revenue from fees for diagnostic services during the nine months ended September 30, 2015. However, we expect to incur substantial net losses for the foreseeable future to further develop and commercialize our cell-free molecular diagnostic technology. We cannot predict the extent of these future net losses, or when we may attain profitability, if at all. If we are unable to generate significant revenue from our cell-free molecular diagnostic technology or attain profitability, we will not be able to sustain operations.

Because of the numerous risks and uncertainties associated with further development and commercialization of our cell-free molecular diagnostic technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our common stock. An investor in our common stock must carefully consider the substantial challenges, risks and uncertainties inherent in the development and commercialization of tests in the medical diagnostic industry. We may never successfully commercialize our cell-free molecular diagnostic technology or any future tests, and our business may fail.

Our ability to successfully commercialize our technology will depend largely upon the extent to which third-party payors reimburse our tests.

Physicians and patients may decide not to order our products unless third-party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid pay a substantial portion of the test price.

Reimbursement by a third-party payor may depend on a number of factors, including a payor’s determination that our product candidates are:

•not experimental or investigational;

•effective;

•medically necessary;

•appropriate for the specific patient;

•cost-effective;

•supported by peer-reviewed publications; and

•included in clinical practice guidelines.

Market acceptance, sales of products based upon our cell-free molecular diagnostic technology, and our profitability may depend on reimbursement policies and health care reform measures. Several entities conduct technology assessments of

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medical tests and devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payors and health care providers as grounds to deny coverage for a test or procedure. The levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, may reimburse the price patients pay for such products could affect whether we are able to commercialize our products. Our product candidates may receive negative assessments that may impact our ability to receive reimbursement of the test. Since each payor makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals may be a time-consuming and costly process. We cannot be sure that reimbursement in the U.S. or elsewhere will be available for any of our products in the future. If reimbursement is not available or is limited, we may not be able to commercialize our products.

If we are unable to obtain reimbursement approval from commercial third-party payors and Medicare and Medicaid programs for our product candidates, or if the amount reimbursed is inadequate, our ability to generate revenues could be limited. During the quarter ended September 30, 2015, we generated minimal revenue from reimbursement from commercial third-party payors for our diagnostic services. However, this may not continue due to the reasons discussed above, and insurers may withdraw their coverage policies or cancel their contracts with us at any time, stop paying for our test or reduce the payment rate for our test, which would reduce our revenue. Moreover, we may depend upon a limited number of third-party payors for a significant portion of our test revenues and if these or other third-party payors stop providing reimbursement or decrease the amount of reimbursement for our test, our revenues could decline.

Our business could be adversely impacted by adoption of new coding for molecular genetic tests.

Reimbursement for our diagnostic services, through the use of our Laboratory Developed Tests (“LDT”), is currently available under the current procedural terminology codes, or CPT codes. If we decide to market our products as a diagnostic kit rather than a LDT, our products would be subject to Food and Drug Administration (“FDA”) regulation as a medical device. If our diagnostic kit were commercially available today, reimbursement would be available under the CPT codes for molecular-based testing. The American Medical Association CPT® Editorial Panel is continuing its process of establishing analyte specific billing codes to replace codes that describe procedures used in performing molecular testing. The adoption of analyte specific codes will allow payers to better determine tests being performed. This could lead to limited coverage decisions or payment denials.

The commercial success of our product candidates will depend upon the degree of market acceptance of these products among physicians, patients, health care payors and the medical community and on our ability to successfully market our product candidates.

We are in the early stages of commercializing our cell-free molecular diagnostic technology as an LDT. However, the use of our cell-free molecular diagnostic technology has never been commercialized for any specific indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not order diagnostic tests based upon our cell-free molecular diagnostic technology, in which event we may be unable to generate significant revenue or become profitable. Acceptance of our cell-free molecular diagnostic technology will depend on a number of factors including:

•acceptance of products based upon our cell-free molecular diagnostic technology by physicians and patients;

• successful integration into clinical practice;

•adequate reimbursement by third parties;

•cost effectiveness;

•potential advantages over alternative treatments; and

•relative convenience and ease of administration.

We will need to make leading physicians aware of the benefits of tests using our technology through published papers, presentations at scientific conferences and favorable results from our clinical studies. In addition, we will need to gain support from thought leaders who believe that testing a urine specimen for these molecular markers will provide superior performance. Ideally, we will need these individuals to publish support papers and articles which will be necessary to gain acceptance of our products. There is no guarantee that we will be able to obtain this support. Our failure to be successful in

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these efforts would make it difficult for us to convince medical practitioners to order cell-free molecular diagnostic tests for their patients and consequently our revenue and profitability will be limited.

We currently have limited experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We have limited experience in marketing products. We intend to continue to develop our in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other molecular diagnostic companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to further grow our internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our product candidates or future products, however, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, they may not have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates

The patents issued to us may not be broad enough to provide any meaningful protection one or more of our competitors may develop more effective technologies, designs or methods without infringing our intellectual property rights and one or more of our competitors may design around our proprietary technologies.

If we are not able to protect our proprietary technology, trade secrets and know-how, our competitors may use our inventions to develop competing products. We own certain patents relating to our cell-free molecular diagnostic technology. However, these patents may not protect us against our competitors, and patent litigation is very expensive. We may not have sufficient cash available to pursue any patent litigation to its conclusion because other than revenue from licensing, milestone and royalty income we currently generate only minimal revenue from our diagnostic services.

We cannot rely solely on our current patents to be successful. The standards that the U.S. Patent and Trademark Office and foreign patent office’s use to grant patents, and the standards that U.S. and foreign courts use to interpret patents, are not the same and are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the U.S. may differ substantially from that obtained in various foreign countries. In some instances, patents have been issued in the U.S. while substantially less or no protection has been obtained in Europe or other countries.

We cannot be certain of the level of protection, if any, which will be provided by our patents if we attempt to enforce them and they are challenged in court where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license. In addition, the type and extent of any patent claims that may be issued to us in the future are uncertain. Any patents which are issued may not contain claims that will permit us to stop competitors from using similar technology.

We are subject to the data privacy, security and breach notification requirements of HIPAA, HITECH and other data privacy and security laws, and the failure to comply with these rules, or allegations that we have failed to do so, could result in civil or criminal sanctions.

Numerous federal and state laws and regulations, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Health Information Technology for Economic and Clinical Health Act, as amended, or HITECH, govern the collection, dissemination, security, use and confidentiality of patient-identifiable health information. As required by HIPAA, the United States Department of Health and Human Services, or HHS, has adopted standards to protect the privacy and security of this health-related information. The HIPAA privacy regulations contain detailed requirements concerning the use and disclosure of individually identifiable health information and the grant of certain rights to patients with respect to such information by "covered entities." Because of our CLIA laboratory we are a covered entity under HIPAA. We have taken actions to comply with the HIPAA privacy regulations including the creation and implementation of policies and procedures, staff training, execution of HIPAA-compliant contractual arrangements with certain service providers and various other measures. Although we believe we are in substantial compliance, ongoing implementation and oversight of these measures involves significant time, effort and expense.

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In addition to the privacy requirements, HIPAA covered entities must implement certain administrative, physical, and technical security standards to protect the integrity, confidentiality and availability of certain electronic health-related information received, maintained, or transmitted by covered entities or their business associates. Although we have taken actions in an effort to be in compliance with these security regulations, a security incident that bypasses our information security systems causing an information security breach, loss of protected health information, or PHI, or other data subject to privacy laws or a material disruption of our operational systems could have a material adverse effect on our business, along with fines. Furthermore, ongoing implementation and oversight of these security measures involves significant time, effort and expense.

Further, HITECH, as implemented in part by an omnibus final rule published in the Federal Register on January 25, 2013, further requires that patients be notified of any impermissible acquisition, access, use, or disclosure of their unsecured PHI that compromises the privacy or security of such information. HHS has established the presumption that all impermissible uses or disclosures of unsecured PHI constitute breaches unless the covered entity or business associate establishes affirmatively through a risk analysis that there is a low probability the information has been compromised. HITECH and implementing regulations specify that such notifications must be made without unreasonable delay and in no case later than 60 calendar days after discovery of the breach. Breaches affecting 500 patients or more must be reported immediately to HHS, which will post the name of the breaching entity on its public website. Furthermore, breaches affecting 500 patients or more in the same state or jurisdiction must also be reported to the local media. If a breach involves fewer than 500 people, the covered entity must record it in a log and notify HHS of such breaches at least annually. These breach notification requirements apply not only to impermissible disclosures of unsecured PHI to outside third parties but also to impermissible internal access to or use of such PHI. All breaches also require written notice to be sent to affected individuals.

The scope of the privacy and security requirements under HIPAA was substantially expanded by HITECH, which also increased penalties for violations. Currently, violations of the HIPAA privacy, security and breach notification standards may result in civil penalties ranging from $100 to $50,000 per violation, subject to a cap of $1,500,000 in the aggregate for violations of the same standard in a single calendar year. The amount of penalty that may be assessed depends, in part, upon the culpability of the applicable covered entity or business associate in committing the violation. HITECH also authorized state attorneys general to file suit on behalf of residents of their states. Applicable courts may be able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. HITECH also mandates that the Secretary of HHS conduct periodic compliance audits of a cross-section of HIPAA covered entities and business associates. Every covered entity and business associate is subject to being audited, regardless of the entity's compliance record.

State laws may impose more protective privacy restrictions related to health information and may afford individuals a private right of action with respect to the violation of such laws. Both state and federal laws are subject to modification or enhancement of privacy protection at any time. We are subject to any federal or state privacy-related laws that are more restrictive than the privacy regulations issued under HIPAA. These statutes vary and could impose additional requirements on us and more severe penalties for disclosures of health information. If we fail to comply with HIPAA, similar state laws or any new laws, including laws addressing data confidentiality, security or breach notification, we could incur substantial monetary penalties and substantial damage to our reputation.

States may also impose restrictions related to the confidentiality of personal information that is not considered PHI under HIPAA, including certain identifying information and financial information of our patients. These state laws may impose additional notification requirements in the event of a breach of such personal information. Failure to comply with such data confidentiality, security and breach notification laws may result in substantial monetary penalties.

HIPAA and HITECH also include standards for common healthcare electronic transactions and code sets, such as claims information, plan eligibility and payment information. Covered entities such as us (with our CLIA laboratory) are required to conform to such transaction set standards.

We may become subject to the Anti-Kickback Statute, Stark Law, FCA, Civil Monetary Penalties Law and may be subject to analogous provisions of applicable state laws and could face substantial penalties if we fail to comply with such laws.

There are several federal laws addressing fraud and abuse that apply to businesses that receive reimbursement from a federal health care program. There are also a number of similar state laws covering fraud and abuse with respect to, for example, private payors, self-pay and insurance. Currently, we receive a minimal amount of revenue related to reimbursement from private payors. However, we may in the future receive reimbursement from a federal health care program, or others. Accordingly, our business could become subject to federal fraud and abuse laws, such as the Anti-Kickback Statute, the Stark Law, the False Claims Act, the Civil Monetary Penalties Law and other similar laws. Moreover, we may already be subject to

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similar state laws. We intend to operate our business, and believe we do operate our business, in compliance with these laws. However, these laws are subject to modification and changes in interpretation, and are enforced by authorities vested with broad discretion. Federal and state enforcement entities have significantly increased their scrutiny of healthcare companies and providers which has led to investigations, prosecutions, convictions and large settlements. We continually monitor developments in this area. If these laws are interpreted in a manner contrary to our interpretation or are reinterpreted or amended, or if new legislation is enacted with respect to healthcare fraud and abuse, illegal remuneration, or similar issues, we may be required to restructure our affected operations to maintain compliance with applicable law. There can be no assurances that any such restructuring will be possible or, if possible, would not have a material adverse effect on our results of operations, financial position, or cash flows.

Anti-Kickback Statute

A federal law commonly referred to as the "Anti-Kickback Statute" prohibits the knowing and willful offer, payment, solicitation or receipt of remuneration, directly or indirectly, in return for the referral of patients or arranging for the referral of patients, or in return for the recommendation, arrangement, purchase, lease or order of items or services that are covered, in whole or in part, by a federal healthcare program such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value such as gifts, discounts, rebates, waiver of payments or providing anything at less than its fair market value. The PPACA amended the intent requirement of the Anti-Kickback Statute such that a person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate the statute. Further, the PPACA now provides that claims submitted in violation of the Anti-Kickback Statute constitute false or fraudulent claims for purposes of the federal False Claims Act, or FCA, including the failure to timely return an overpayment. Many states have adopted similar prohibitions against kickbacks and other practices that are intended to influence the purchase, lease or ordering of healthcare items and services reimbursed by a governmental health program or state Medicaid program. Some of these state prohibitions apply to remuneration for referrals of healthcare items or services reimbursed by any third-party payor, including commercial payors and self-pay patients.

Because we may accept funds from governmental health programs, we may become subject to the Anti-Kickback Statute. Violations of the Anti-Kickback Statute can result in exclusion from Medicare, Medicaid or other governmental programs as well as civil and criminal penalties, such as $25,000 per violation, and FCA liability. If in violation, we may be required to enter into a corporate integrity agreement, or CIA. Any such sanctions or obligations contained in a CIA could have a material adverse effect on our business, financial condition and results of operations.

Stark Law

Section 1877 of the Social Security Act, or the Stark Law, prohibits a physician from referring a patient to an entity for certain "designated health services" reimbursable by Medicare if the physician (or close family members) has a financial relationship with that entity, including an ownership or investment interest, a loan or debt relationship or a compensation relationship, unless an exception to the Stark Law is fully satisfied. The designated health services covered by the law include, among others, laboratory and imaging services. Some states have self-referral laws similar to the Stark Law for Medicaid claims and commercial claims.

Violation of the Stark Law may result in prohibition of payment for services rendered, a refund of any Medicare payments for services that resulted from an unlawful referral, $15,000 civil monetary penalties for specified infractions, criminal penalties, and potential exclusion from participation in government healthcare programs, and potential false claims liability. The repayment provisions in the Stark Law are not dependent on the parties having an improper intent; rather, the Stark Law is a strict liability statute and any violation is subject to repayment of all amounts arising out of tainted referrals. If physician self-referral laws are interpreted differently or if other legislative restrictions are issued, we could incur significant sanctions and loss of revenues, or we could have to change our

arrangements and operations in a way that could have a material adverse effect on our business, prospects, damage to our reputation, results of operations and financial condition.

False Claims Act

The FCA prohibits providers from, among other things, (1) knowingly presenting or causing to be presented, claims for payments from the Medicare, Medicaid or other federal healthcare programs that are false or fraudulent; (2) knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the federal government; or (3) knowingly making, using or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. The “qui tam” or “whistleblower” provisions of the FCA allow private individuals to bring actions under the FCA on behalf of the government. These private parties are entitled to

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share in any amounts recovered by the government, and, as a result, the number of "whistleblower" lawsuits that have been filed against providers has increased significantly in recent years. Defendants found to be liable under the FCA may be required to pay three times the actual damages sustained by the government, plus civil penalties ranging between $5,500 and $11,000 for each separate false claim.

There are many potential bases for liability under the FCA. The government has used the FCA to prosecute Medicare and other government healthcare program fraud such as coding errors, billing for services not provided, and providing care that is not medically necessary or that is substandard in quality. The PPACA also provides that claims submitted in connection with patient referrals that result from violations of the Anti-Kickback Statute constitute false claims for the purpose of the FCA, and some courts have held that a violation of the Stark law can result in FCA liability, as well. In addition, a number of states have adopted their own false claims and whistleblower provisions whereby a private party may file a civil lawsuit in state court. We are required to provide information to our employees and certain contractors about state and federal false claims laws and whistleblower provisions and protections.

Civil Monetary Penalties Law

The Civil Monetary Penalties Law prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person or entity knows or should know is likely to influence the beneficiary's selection of a particular provider or supplier of items or services reimbursable by a federal or state healthcare program. This broad provision applies to many kinds of inducements or benefits provided to patients, including complimentary items, services or transportation that are of more than a nominal value. This law could affect how we have to structure our operations and activities.

Our common stock price may be volatile and could fluctuate widely in price, which could result in substantial losses for investors.

The market price of our ordinary shares historically has been, and we expect will continue to be, subject to significant fluctuations over short periods of time. These fluctuations may be due to various factors, many of which are beyond our control, including:

•technological innovations or new products and services by us or our competitors;

•clinical trial results relating to our tests or those of our competitors;

•announcements or press releases relating to the industry or to our own business or prospects;

•coverage and reimbursement decisions by third party payors, such as Medicare and other managed care organizations;

•regulation and oversight of our product candidates and services, including by the FDA, Centers for Medicare and Medicaid Services ("CMS") and comparable ex-U.S. agency;

•FDA, CMS and comparable ex-U.S. agency regulation and oversight of our products and services;

•the establishment of partnerships with clinical reference laboratories;

•health care legislation;

•intellectual property disputes;

•additions or departures of key personnel;

•sales of our common stock;

•our ability to integrate operations, technology, products and services;

•our ability to execute our business plan;

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•operating results below expectations;

•loss of any strategic relationship;

•industry developments;

•economic and other external factors; and

•period-to-period fluctuations in our financial results.

In addition, market fluctuations, as well as general political and economic conditions could adversely affect the market price of our securities. Because we are a development stage company with no revenue from operations to date, other than licensing, milestone and royalty income and a minimal amount from our diagnostic services, you should consider any one of these factors to be material. Our stock price may fluctuate widely as a result of any of the foregoing.

We may become subject to federal and state tax assessments, penalties and interest related to issues with respect to certain executive compensation.

During our internal review process, contingencies were identified regarding various federal and state tax exposures related to issues with respect to certain executive compensation. We have not recorded any accrued liabilities related to the potential federal and state tax exposure. If we become subject to tax assessment, penalties and interest by federal and state tax authorities in the future, our results of operations, financial performance and cash flows could be potentially materially adversely affected.

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, 2015 filed on November 9, 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.

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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 9, 2015

By: /s/ Antonius Schuh
Antonius Schuh
Chief Executive Officer

TROVAGENE, INC.

November 9, 2015

By: /s/ Stephen Zaniboni
Stephen Zaniboni
Chief Financial Officer