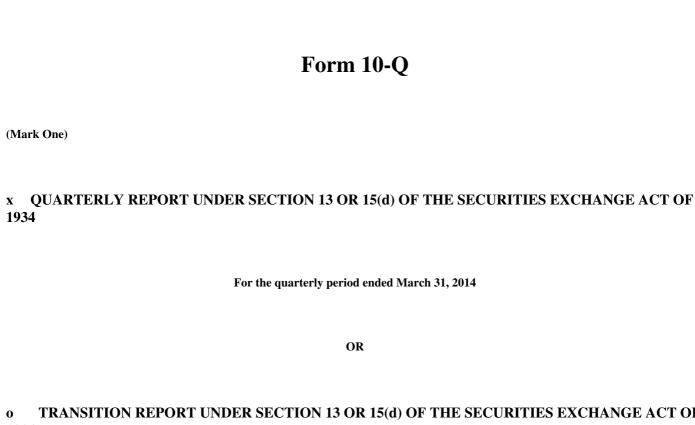
Trovagene, Inc. Form 10-Q May 12, 2014 Table of Contents

# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549



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

> For the transition period from to

**COMMISSION FILE NUMBER 000-54556** 

# TROVAGENE, INC.

(Exact Name of small business issuer as specified in its charter)

Delaware

27-2004382

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

11055 Flintkote Avenue, Suite A, San Diego, California 92121

(Address of principal executive offices) (Zip Code)

Issuer s telephone Number: (858) 952-7570

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

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

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

Large accelerated filer o

Accelerated filer x

Non-accelerated filer o (Do not check if a smaller reporting company)

Smaller reporting company "

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 May 9, 2014 the issuer had 18,902,991 shares of Common Stock issued and outstanding.

## TROVAGENE, INC.

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## TROVAGENE, INC.

## (A Development Stage Company)

## CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,871,122	\$ 25,836,937
Accounts receivable	129,303	78,994
Prepaid expenses and other assets	262,188	152,789
Total current assets	23,262,613	26,068,720
Property and equipment, net	859,645	750,565
Other assets	336,450	336,450
Total assets	\$ 24,458,708	\$ 27,155,735
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 427,424	\$ 286,608
Accrued expenses	1,403,848	1,524,092
Current portion of long-term debt	200,792	198,166
Total current liabilities	2,032,064	2,008,866
Long-term debt, less current portion	274,852	322,998
Derivative financial instruments	4,399,025	4,431,871
Total liabilities	6,705,941	6,763,735
Commitments and contingencies (Note 9)		
Stockholders equity		
Preferred stock, \$0.001 par value, 20,000,000 shares authorized; 60,600 shares outstanding at March 31, 2014 and December 31, 2013; designated as Series A Convertible Preferred Stock with liquidation preference of \$606,000 at March 31,		
2014 and December 31, 2013	60	60
Common stock, \$0.0001 par value, 150,000,000 shares authorized; 18,902,782 shares issued		
and outstanding at March 31, 2014 and December 31, 2013	1,890	1,890
Additional paid-in capital	87,993,233	87,433,460
Deficit accumulated during the development stage	(70,242,416)	(67,043,410)
Total stockholders equity	17,752,767	20,392,000
Total liabilities and stockholders equity	\$ 24,458,708	\$ 27,155,735

See accompanying notes to the unaudited financial statements.

# TROVAGENE, INC. (A Development Stage Company)

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

		Three Months Ended March 31, 2014 2013			Period from August 4, 1999 (Inception) through March 31, 2014
Royalty income	\$	110,953	\$	119,123 \$	1,295,673
Milestone fees					150,000
License fees					1,383,175
Total revenues		110,953		119,123	2,828,848
Costs and expenses:					
Research and development		1,442,521		802,245	22,839,561
Purchased in-process research and development related party					2,666,869
Selling and marketing		569,590		360,459	2,606,284
General and administrative		1,358,480		1,346,258	32,244,100
Total operating expenses		3,370,591		2,508,962	60,356,814
Loss from operations		(3,259,638)		(2,389,839)	(57,527,966)
Interest income		2,391			272,937
Interest expense		(9,496)			(1,351,873)
Gain on disposal of equipment		44,101			25,160
Amortization of deferred debt costs and original issue					(2.246.220)
discount		22.046		1 270 142	(2,346,330)
Change in fair value of derivative instruments-warrants		32,846		1,279,143	(6,546,067)
Gain on extinguishment of debt					623,383
Liquidated damages and other forbearance agreement settlement costs					(1.750.111)
		(2.190.706)		(1.110.606)	(1,758,111)
Net loss		(3,189,796)		(1,110,696)	(68,608,867)
Preferred stock dividend		(9,210)		(5,885)	(385,208)
Cumulative effect of early adopting ASC Topic 815-40					(455,385)
Series A Convertible Preferred stock conversion rate					
change accreted as a dividend					(792,956)
Net loss attributable to common stockholders	\$	(3,199,006)	\$	(1,116,581) \$	(70,242,416)
	ф	(0.17)	Ф	(0.05)	
Net loss per common share-basic and diluted	\$	(0.17)	\$	(0.07)	
Weighted average shares outstanding - basic and diluted		18,902,782		15,510,340	

See accompanying notes to the unaudited financial statements.

## TROVAGENE, INC.

(A Development Stage Company)

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

## (Unaudited)

	Three M Ended Me 2014	2013	Period from August 4, 1999 (Inception) through March 31, 2014
Operating activities			
Net loss	\$ (3,189,796)	\$ (1,110,696)	\$ (68,608,867)
Adjustments to reconcile net loss to net cash used in operating activities:			
Net gain on disposal of fixed assets	(44,101)		(25,160)
Depreciation and amortization	53,528	17,779	447,689
Stock based compensation expense	559,773	341,475	14,551,602
Founders compensation contributed to equity			1,655,031
Donated services contributed to equity			829,381
Settlement of consulting services in stock			478,890
Amortization of deferred debt costs and original issue			
discount			2,346,330
Liquidated damages and other forbearance agreement			
settlement costs paid in stock			1,758,111
Interest expense on convertible debentures paid in stock			757,198
Change in fair value of financial instruments	(32,846)	(1,279,143)	6,546,067
Gain on extinguishment of debt			(623,383)
Purchased in process research and development			• ***
expense-related party			2,666,869
Stock issued in connection with payment of deferred			20.246
salary			28,346
Stock issued in connection with settlement of legal fees			100,000
Stock and warrant issued in connection with consulting		100.701	651 100
services		198,791	651,180
Changes in operating assets and liabilities:		(15( (04)	(44.250)
Increase in other assets	(50,309)	(156,694)	(44,250)
(Increase) decrease in accounts receivable	( ) /	110,317	(129,304)
Increase in prepaid expenses	(109,399)	(67,043)	(262,188)
Increase in accounts payable and accrued expenses	14,479	316,554	1,748,788
Net cash used in operating activities	(2,798,671)	(1,628,660)	(35,127,670)
Investing activities:			
Assets acquired in Etherogen, Inc. merger			(104,700)
Capital expenditures, net	(118,507)	(93,351)	(1,282,174)
Net cash used in investing activities	(118,507)	(93,351)	(1,386,874)
a to the same does not not to the same does not to the same does not not not to the same does not	(110,007)	(50,001)	(1,200,07.1)
Financing activities:			
Proceeds from sale of 6% convertible debenture			2,335,050
Debt issuance costs			(297,104)
Proceeds from sale of common stock, net of expenses			51,585,195

Proceeds from exercise of warrants				66,505		3,599,831
Proceeds from exercise of options						38,849
Proceeds from a non-exclusive selling agent s agreement						142,187
Net borrowings (repayments) under equipment line of						
credit		(48,637)				467,327
Costs associated with recapitalization						(362,849)
Proceeds from sale of preferred stock						2,771,000
Payment of finders fee on preferred stock						(277,102)
Redemption of common stock						(500,000)
Payment of preferred stock dividends						(116,718)
Net cash (used in) provided by financing activities		(48,637)		66,505		59,385,666
Net change in cash and equivalent		(2,965,815)		(1,655,506)		22,871,122
Cash and cash equivalents Beginning of period		25,836,937		10,819,781		
Cash and cash equivalents End of period	\$	22,871,122	\$	9,164,275	\$	22,871,122
Supplementary disclosure of cash flow activity:						
Cash paid for taxes	\$	2,400	\$	7,650	\$	10,050
•						
Cash paid for interest	\$	6,601	\$		\$	16,060
Supplemental disclosure of non-cash investing and						
financing activities:						
Issuance of 41,750 shares of common stock for prior						
year Board of Directors fees in lieu of cash payment	\$		\$		\$	125,250
Conversion of \$2,335,050 of 6% debentures	\$		\$		\$	1,130,164
Issuance of 125,000 shares of common stock pursuant to						
Asset Purchase Agreement with MultiGen						
Diagnostics, Inc.	\$		\$		\$	187,500
Issuance of 2,043,797 shares of common stock pursuant						
to Agreement and Plan of Merger with Etherogen, Inc.	\$		\$		\$	2,771,389
Reclassification of derivative financial instruments to			•		•	, ,
additional paid in capital	\$		\$		\$	(8,735,334)
Correction of error in derivative financial instruments	\$		\$		\$	(274,967)
Series A Preferred beneficial conversion feature			•			
accreted as a dividend	\$		\$		\$	792,956
Issuance of common stock from net exercise of warrants	\$		\$		\$	2,
Preferred stock dividends accrued	\$	9,210	\$	5,885	\$	230,250
Interest paid in common stock	\$	>,==0	\$	2,303	\$	1,325,372
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See accompanying notes to the unaudited financial statements.

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Business Overview

resistance over time.

## TROVAGENE, INC.

(A Development Stage Company)

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Business Overview, Basis of Presenta	tion and Liquidity	

Trovagene, Inc. ( Trovagene or the Company ) is focused on developing and commercializing its precision cancer monitoring technology, which can inform oncologists and guide treatment decisions by determining a patient s mutational status and tracking therapeutic response and

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

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Trovagene, which include its wholly owned subsidiaries Xenomics, Inc., a California corporation, Xenomics Europa Ltd, (an inactive subsidiary formed in the United Kingdom and liquidated) and Etherogen, Inc. have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). All intercompany balances and transactions have been eliminated. Certain items in the comparable prior period s financial statements have been reclassified to conform to the current period s presentation. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements as of December 31, 2013 and 2012 and for each of the three years ended December 31, 2013 and from inception (August 4, 1999) to December 31, 2013 included in the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2014. The accompanying condensed consolidated financial statements have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at March 31, 2014, and for all periods presented herein, have been made. The results of operations for the periods ended March 31, 2014 and 2013 are not necessarily indicative of the operating results for the full year.

Reverse Stock Split

On May 24, 2012, the Board of Directors approved a 1-for-6 reverse stock split of the Company s issued and outstanding common stock effective on May 29, 2012. All the relevant information relating to number of shares and per share information contained in these condensed consolidated financial statements has been retrospectively adjusted to reflect the reverse stock split for all periods presented.

Liquidity

Trovagene s condensed consolidated financial statements as of March 31, 2014 have been prepared under the assumption that Trovagene will continue as a going concern. The Company s ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate additional revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at its current projected cash expenditure levels.

Cash used in operating activities was \$2,798,671 and \$1,628,660, for the three months ended March 31, 2014 and 2013, respectively. During the three months ended March 31, 2014 and 2013, the Company incurred a net loss of \$3,189,796 and \$1,110,696, respectively.

To date, Trovagene s sources of cash have been primarily related to financing activities, including the sale of debt and equity securities, debt borrowings and proceeds from exercise of warrants and options. During the three months ended March 31, 2014 cash used by financing activities was \$48,637 and resulted from debt repayments, while in the same period of the prior year, \$66,505 was provided by the exercise of warrants. The Company cannot be certain that additional funding will be available on acceptable terms, or

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at all. To the extent that the Company can raise additional funds by issuing equity securities, the Company s stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact the Company s ability to conduct its business.

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

- Seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and
- Relinquish licenses or otherwise dispose of rights to technologies, product candidates or products that the Company would otherwise seek to develop or commercialize themselves, on unfavorable terms.

The Company has approximately \$21.9 million of cash and cash equivalents at April 30, 2014.

#### 2. Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, *Earnings per Share*, for all periods presented. In accordance with this guidance, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. In a period where there is a net loss position, diluted weighted-average shares are the same as basic weighted-average shares. Shares used in calculating basic and diluted net loss per common share for the three months ended March 31 exclude as antidilutive the following share equivalents:

	March 31,		
	2014	2013	
Options to purchase Common Stock	4,423,638	3,962,710	
Warrants to purchase Common stock	6,233,483	7,009,824	
Series A Convertible Preferred Stock	63,125	81,354	
	10,720,246	11,053,888	

#### 3. Accounting for Share-Based Payments

## Stock Options

ASC Topic 718 Compensation Stock Compensation requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. ASC Topic 718 did not change the way Trovagene accounts for non-employee stock-based compensation. Trovagene accounts for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 Equity-Based Payment to Non-Employees whereas the value of the stock compensation is based upon the measurement date as determined at either: a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being marked to market quarterly until the measurement date is determined.

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

	Three Months Ended March 31,					
		2014		2013		
Included in research and development expense	\$	189,635	\$	122,317		
Included in selling and marketing expense		22,680		21,717		
Included in general and administrative expense		347,458		197,441		
Total stock-based compensation expense	\$	559,773	\$	341,475		

The unrecognized compensation cost related to non-vested stock options outstanding at March 31, 2014 and 2013, net of expected forfeitures, was \$3,695,076 and \$3,504,395, respectively, to be recognized over a weighted-average remaining vesting period of approximately three and four years, respectively. The remaining contractual term of outstanding options as of March 31, 2014 was approximately 6.5 years.

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

	Three Months I March 31	
	2014	2013
Risk-free interest rate	1.5-1.6%	0.82-0.89%
Dividend yield	0%	0%
Expected volatility	83%	97%
Expected term (in years)	5.0 yrs.	5.0 yrs.

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

	Number of Options	Weighted Average Exercise Price Per Share	Intrinsic Value
Balance outstanding, December 31, 2013	4,287,545 \$	5.18	
Granted	167,870	6.13	
Forfeited	(31,777)	6.16	
Balance outstanding, March 31, 2014	4,423,638 \$	5.20	\$ 5,860,704
Exercisable at March 31, 2014	2,520,235 \$	5.52	\$ 3,617,109

#### Warrants

As of March 31, 2014 and December 31, 2013, the Company had 6,233,483 warrants outstanding at a weighted average exercise price of \$3.87. The remaining contractual term of outstanding warrants as of March 31, 2014 was approximately 4 years.

## 4. Stockholders Equity

#### **Common Stock**

On January 25, 2013, the Company filed a Form S-3 Registration Statement to offer and sell in one or more offerings, any combination of common stock, preferred stock, warrants, or units having an aggregate initial offering price not exceeding \$150,000,000. The preferred stock, warrants, and units may be convertible or exercisable or exchangeable for common stock or preferred stock or other Trovagene securities. This form was declared effective on February 4, 2013. In addition, in connection with the Form S-3, the Company entered into an agreement with Cantor Fitzgerald & Co. (Agent) on January 25, 2013 to issue and sell up to \$30,000,000 of shares of common stock through them. As payment for its services, the Agent is entitled to a 3% commission on gross proceeds. There were no sales of common stock during the quarter ended March 31, 2014.

#### 5. Asset Purchase Agreement

On February 1, 2012, the Company entered into an asset purchase agreement with MultiGen Diagnostics, Inc. The Company determined that the acquired asset did not meet the definition of a business, as defined in ASC 805, *Business Combinations* and was accounted for under ASC 350, *Intangibles- Goodwill and Other*. In connection with the acquisition, the Company issued 125,000 shares of restricted common stock to MultiGen. In addition, up to an additional \$3.7 million may be paid in a combination of common stock and cash to MultiGen upon the achievement of specific sales and earnings targets. In addition, in connection with the acquisition, the Company entered into a Reagent Supply Agreement dated as of February 1, 2012 pursuant to which MultiGen will supply and deliver reagents to be used in connection with a Clinical Laboratory Improvement Amendment (CLIA) laboratory. The total purchase consideration was determined to be \$187,500 which was paid in the Company s common stock and allocated to an indefinite lived intangible asset related to the CLIA license.

Under ASC Topic 805, Business Combinations, the Company was required to assess the fair value of the assets acquired and the contingent consideration at the date of acquisition. Therefore, the Company assessed the fair value of the assets purchased and concluded that the purchase price would be allocated entirely to one intangible asset, a CLIA license. The contingent consideration of the \$3.7 million milestone was determined to have no fair value by applying a weighted average probability on the achievement of the milestones developed during the valuation process. The Company assesses the fair value of the contingent consideration at each quarter and makes adjustments as necessary until the milestone dates have expired. As of March 31, 2014, no adjustments to the fair value of the contingent consideration have been necessary, and therefore the fair value of the contingent consideration remains unchanged.

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#### 6. Derivative Financial Instruments - Warrants

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, Derivatives and Hedging: Contracts in Entity s Own Equity (ASC Topic 815-40). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity s own stock, which would qualify as a scope exception under ASC Topic 815-10.

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

The Company estimates the fair value of the warrants issued in connection with certain of its debentures using the Black-Scholes model in order to determine the associated derivative instrument liability and change in fair value described above. The range of assumptions used to determine the fair value of the warrants at the end of each three month period, March 31, 2014 and 2013 were as follows:

	Three Months Ended March 31,					
	2014					
Estimated fair value of Trovagene common stock	\$	5.73	\$		6.26	
Expected warrant term	4	.76 years		0.82	5.76 years	
Risk-free interest rate		1.73%		0.	.11-1.01%	
Expected volatility		83%			97%	
Dividend yield		0%			0%	

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

Date	Description	Warrants	Derivative Instrument Liability
December 31, 2013	Balance of derivative financial instruments liability	1,013,961	\$ 4,431,871
	Change in fair value of warrants during the quarter recognized as a gain in the condensed consolidated statement of operations		(32,846)
March 31, 2014	Balance of derivative financial instruments liability	1,013,961	\$ 4,399,025

#### 7. Fair Value Measurements

Fair value of financial instruments

The following table presents the Company s assets and liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of March 31, 2014 and December 31, 2013:

	Fair Value Measurements at March 31, 2014							
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)		Significant Other S Observable		Significant Unobservable Inputs (Level 3)			Total
Assets:								
Money market fund (1)	\$	22,580,276	\$		\$		\$	22,580,276
Total Assets	\$	22,580,276	\$		\$		\$	22,580,276
Liabilities:								
Derivative liabilities related to warrants			\$		\$	4,399,025	\$	4,399,025
Total Liabilities	\$		\$		\$	4,399,025	\$	4,399,025
			9					

# Fair Value Measurements at

				Decemb	er 31, 20	13			
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)			Total	
Assets:									
Money market fund (1)	\$	25,703,330	\$		\$		\$	25,703,330	
Total Assets	\$	25,703,330	\$		\$		\$	25,703,330	
Liabilities:									
Derivative liabilities related to warrants			\$		\$	4,431,871	\$	4,431,871	
Total Liabilities	\$		\$		\$	4,431,871	\$	4,431,871	

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

The following table sets forth a summary of changes in the fair value of the Company s Level 3 liabilities for the three months ended March 31, 2014:

	Balance at December 31,	Unrealized	Balance at March 31,
Description	2013	Gain	2014
Derivative liabilities related to			
Warrants	\$ 4,431,871	\$ (32,846)	\$ 4,399,025

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

#### 8. Debt

Equipment Line of Credit

In June 2013, the Company entered into a Loan and Security Agreement with Silicon Valley Bank that provides for cash borrowings for equipment of up to \$1.0 million, secured by the equipment financed. As of March 31, 2014, \$515,964 has been borrowed under the agreement. As of March 31, 2014, amounts due under the agreement include \$200,792 in current liabilities and \$274,852 in long-term liabilities, which includes \$8,317 of accrued interest.

Under the terms of the agreement, interest is the greater of 5% or 4.6% above the U.S. Treasury Note as of the date of each borrowing. The weighted average interest rate of the borrowings is 5.28% as of March 31, 2014. 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 are subject to principal and interest payments immediately over a 30 month period following the advance. The Company has an obligation to make a final payment equal to 7% of total amounts borrowed at the loan maturity date and the final payment is being accrued over the term of the loans using the effective-interest method.

At March 31, 2014, Trovagene was in compliance with all covenants under the Loan Agreement. The Company is subject to certain nonfinancial covenants and a material adverse change clause.

The Company recorded approximately \$9,500 in interest expense related to the Loan and Security Agreement during the three months ended March 31, 2014.

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9. Commitments and Contingencies
Executive and Consulting Agreements
The Company has contracted with various consultants and third parties, including the Company s Chief Executive Officer ( CEO ) and Chief Financial Officer ( CFO ). The executive agreements with the CEO and CFO provide for severance payments.
Lease Agreement
The Company leases approximately 8,300 square feet of office space at a monthly rental rate of approximately \$18,300 to \$20,000 during the remaining term of the lease, through December 2017.

During 2012, the Company entered into research agreements with University of Texas MD Anderson Cancer Center (MDACC) to provide samples and evaluate methods used by the Company in identification of pancreatic cancer mutations, as well as to measure the degree of concordance between results of cell-free DNA mutations analysis from urine samples and tumor tissue. During 2013, the agreements were amended to increase the scope of the agreements. Under these agreements, the Company has committed to pay approximately \$266,000 for the services performed by MDACC. As of March 31, 2014, the Company has incurred and recorded approximately \$216,000 of research and development expenses related to these agreements.

Research and Development Agreements

In April 2013, the Company entered into a research and development agreement with PerkinElmer Health Sciences, Inc. (PerkinElmer) pursuant to which the Company will design an assay, based on the Company's urine-based cell-free molecular diagnostic technology, to determine the risk for developing hepatocellular carcinoma. In addition, the Company has granted PerkinElmer an exclusive option (the HCC Option) to obtain an exclusive royalty-bearing license to use the Company's technology within the hepatocellular carcinoma field (the HCC Field) as well as other fields. Together with PerkinElmer we will jointly validate the assay and evaluate the potential of combining our urine-based cell-free molecular diagnostic technology with PerkinElmer's technology for automation of nucleic acid isolation. PerkinElmer will pay us milestone payments. The Company recognizes milestone payments received from PerkinElmer as a reduction in research and development costs as the services are performed. Amounts received in advance of services performed are recorded as accrued liabilities until the services for which the payment has been received have been performed. As of March 31, 2014, the Company has received milestone payments related to this agreement of approximately \$90,000 and incurred and recorded approximately \$90,000 of research and development costs. A notice of termination was received in March 2014 terminating the agreement. No further commitments exist from either party.

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

or the one year anniversary of the agreement unless extended by mutual written agreement.

In August 2013, the Company entered into a clinical trial agreement with the University of Southern California (USC), pursuant to which USC will provide the principal investigator and conduct the clinical trial related to the genetic characterization of metastatic colorectal cancers. Under the agreement, the Company may pay USC approximately \$232,000 for services provided. Through March 31, 2014 the Company has incurred and recorded approximately \$1,300 of research and development expense related to this agreement.

In December 2013, the Company entered into a clinical trial agreement with US Oncology Research LLC ( USOR ), pursuant to which USOR will provide the principal investigator and conduct the clinical trial related to the examining the utility of transrenal quantitative KRAS testing in disease monitoring in patients with metastatic pancreatic cancer. Under the agreement, the Company may pay USOR approximately \$270,000 for services provided. As of March 31, 2014 the Company has incurred and recorded approximately \$30,000 of research and development expense related to this agreement.

#### 10. Subsequent Events

On May 8, 2014, we entered into a Patent Assignment and License Agreement, effective as of April 23, 2014, with GenSignia IP Ltd., a United Kingdom company, pursuant to which the Company assigned all of its miRNA patents, including methods of using miRNA for detection of in vivo cell death and detecting cell-free miRNA in urine and blood. Concurrent with the assignment, GenSignia granted to the Company an exclusive, world-wide, royalty-free, fully paid, perpetual license under the transferred patents in the urine field. Pursuant to the agreement, GenSignia will pay the Company a low single digit royalty on net sales and will pay an aggregate \$6.5 million in milestone payments upon the achievement of up to \$150 million in net sales. GenSignia shall be responsible for the preparation, filing and maintenance of all patents under the agreement. Antonius Schuh, the Company s CEO and a director, is a director of GenSignia. Dr. Schuh did not participate in any negotiations with respect to the agreement and recused himself from any director vote in connection with the agreement.

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

#### **Forward-Looking Statements**

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

In addition, our business and financial performance may be affected by the factors that are discussed under Risk Factors in the Annual Report on Form 10-K for the year ended December 31, 2013, filed on March 17, 2014. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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

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

#### Overview

We are focused on developing and commercializing our precision cancer monitoring technology, which can inform oncologists; and guide treatment decisions by determining a patient s mutational status and tracking therapeutic response and resistance over time.

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

technology includes methods of extracting, purifying, preparing, and detecting cell-free DNA and RNA mutations in urine.

From August 4, 1999 (inception) through March 31, 2014, we have sustained a cumulative total deficit of \$70,242,416. From inception through March 31, 2014, we have generated minimal revenues and expect to incur additional losses to perform further research and development activities. During 2014, we have advanced our business with the following activities:

- We introdued our non-invasive cancer monitoring platform with the release of our first multiplexed oncogene mutation assay using next generation sequencing. This allows us to leverage the scalability of our proprietary platform and next generation sequencing to introduce a full line of multiplexed urine-based oncogene mutation assays.
- We entered into a strategic partnership with Catholic Health Initiatives Center for Translational Research to clinically evaluate non-invasive genomic diagnostics to improve cancer care. The partnership seeks to establish clinical and health economic benefits for potential adoption in cancer management strategies.

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

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

## **Off-Balance Sheet Arrangements**

We had no off-balance sheet arrangements as of March 31, 2014.

#### **Critical Accounting Policies**

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS of our Annual Report on Form 10-K as of and for the year ended December 31, 2013, filed with the SEC on March 17, 2014. There have been no changes to our critical accounting policies since December 31, 2013.

## RECENT ACCOUNTING PRONOUNCEMENTS

There are no recent accounting pronouncements affecting the Company.

#### RESULTS OF OPERATIONS

Three Months Ended March 31, 2014 and 2013

#### Revenues

Our total revenues were \$110,953 and \$119,123 for the three months ended March 31, 2014 and 2013, respectively, and consisted of royalty income. Royalty income decreased by \$8,170 in the three months ended March 31, 2014, primarily due to timing of royalty payments received. There was no milestone, license fee or diagnostic revenue in the three months ended March 31, 2014 and 2013.

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

## Research and Development Expenses

Research and development expenses consisted of the following:

	Three Months Ended March 31,						
		2014		2013		Increase	
Salaries and staff costs	\$	543,791	\$	304,312	\$	239,479	
Stock-based compensation		189,635		122,317		67,318	
Outside services, consultants and lab supplies		551,250		268,642		282,608	
Facilities		130,742		91,762		38,980	
Travel and scientific conferences		25,804		15,212		10,592	
Other		1,299				1,299	
Total research and development	\$	1,442,521	\$	802,245	\$	640,276	

Research and development expenses increased by \$640,726 to \$1,442,521 for the three months ended March 31, 2014 from \$802,245 for the same period in 2013. Substantially all of the increase resulted from the expansion of our research and development efforts to support the clinical collaborations we have entered into related to validating our tests to detect certain types of cancer in urine samples. As a result of these collaborations, we increased the average number of our internal research and development personnel from seven to thirteen, 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 N	Months Ended March	31,	
	2014		2013		Increase/(Decrease)
Salaries and staff costs	\$ 318,518	\$	185,970	\$	132,548
Stock-based compensation	22,680		21,717		963
Outside services and consultants	106,007		70,645		35,362
Facilities	28,068		22,253		5,815
Trade shows, conferences and marketing	65,198		12,582		52,616
Travel	28,877		20,327		8,550
Other	242		26,965		(26,723)
Total sales and marketing	\$ 569,590	\$	360,459	\$	209,131

Selling and marketing expenses increased by \$209,131 to \$569,590 for the three months ended March 31, 2014 from \$360,459 for the same period in 2013. We have increased our sales and marketing headcount and costs as we expand our efforts to inform the major cancer centers in the United States of our current and future product offerings. We expect these costs to increase as we continue to market and sell our tests.

## General and Administrative Expenses

General and administrative expenses consisted of the following:

		Three 1	Months Ended Marc	h 31,	
	2014		2013		Increase/(Decrease)
Salaries and staff costs	\$ 175,727	\$	117,448	\$	58,279
Board of Directors fees	65,374		63,855		1,519
Stock-based compensation	347,458		396,233		(48,775)
Outside services and consultants	353,922		309,044		44,878
Legal and accounting fees	203,854		335,731		(131,877)
Facilities and insurance	59,233		53,121		6,112
Travel	59,264		40,410		18,854
Fees, licenses, taxes and other	93,648		30,416		63,232
Total general and administrative	\$ 1,358,480	\$	1,346,258	\$	12,222

General and administrative expenses increased by \$12,222 to \$1,358,480 for the three months ended March 31, 2014, from \$1,346,258 for the same period in 2013. Continued patent filing and maintenance as well as the costs associated with being a publicly traded company, such as additional costs for insurance, NASDAQ fees and Sarbanes-Oxley compliance have added to our general and

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administrative expenses in comparison to the same period of the prior year. We expect our general and administrative costs to increase as a result of our accelerated filer status and as we raise more capital.

#### Change in Fair Value of Derivative Instruments - Warrants

We have issued securities that are accounted for as derivative liabilities. As of March 31, 2014, the derivative liabilities related to securities issued were revalued to \$4,399,025, resulting in a net decrease in value of \$32,846 from December 31, 2013, based primarily upon the change in our stock price from \$5.74 at December 31, 2013 to \$5.73 at March 31, 2014 and the changes in the expected term and risk free interest rates for the expected term. The decrease in value was recorded as non-operating gain for the three months ended March 31, 2014.

#### Net Loss

Net loss and per share amounts were as follows:

	Th	ree M	onths Ended March 3	31,	
	2014		2013		Increase
Net loss attributable to common shareholders	\$ (3,199,006)	\$	(1,116,581)	\$	2,082,425
Net loss per common share: basic and diluted	\$ (0.17)	\$	(0.07)	\$	0.10
Weighted average shares: basic and diluted	18,902,782		15,510,340		3,392,442

The \$2,082,425 increase in net loss attributable to common shareholders and \$0.10 increase in net loss per share in 2014 compared to 2013 reflected a slight decrease in revenues, an increase in operating expenses, and a decrease in the gain from the change in fair value in derivative liabilities. Net loss per share in 2014 was also impacted by the sale and issuance of approximately 3.4 million shares of common stock resulting from the sales of stock during the third quarter of 2013, and exercise of stock options and warrants from April 1, 2013 through December 31, 2013.

## LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2014, we had \$22,871,122 in cash and cash equivalents. Net cash used in operating activities for the three months ended March 31, 2014 was \$2,798,671, compared to \$1,628,660 for the three months ended March 31, 2013. Our use of cash was primarily a result of the net loss of \$3,189,796 for the three months ended March 31, 2014, adjusted for non-cash items related to stock-based compensation of \$559,773, depreciation and amortization of \$53,528 and the gain from the change in fair value of derivatives of \$32,846. The changes in our operating assets and liabilities consisted of higher accounts payable and accrued expenses, 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 \$118,507 in cash during the three months ended March 31, 2014, compared to \$93,351 for the same period in 2013.

Net cash used by financing activities was \$48,637 during the three months ended March 31, 2014, compared to net cash provided by financing activities of \$66,505 in 2013. Financing activities during the three months ended March 31, 2014 related to net repayments under an equipment line of credit, while financing activities during the same period of the prior year were from proceeds received upon the exercise of warrants.

As of March 31, 2014, and December 31, 2013, we had working capital of \$21,230,549 and \$24,059,854, respectively. As of April 30, 2014, our working capital was \$20,303,849.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of our research and development programs and ramp up of our sales and marketing function. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates, to fund the existing working capital deficit and to continue to fund operations at our current cash expenditure levels. To date, our sources of cash have been primarily limited to the sale of equity securities and debentures. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more of product candidates; (ii) seek collaborators for

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product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Public Offering and Controlled Equity Offering

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

#### CONTRACTUAL OBLIGATIONS

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, 2013.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

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

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

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

institutions, we cannot provide assurance that we will not experience losses on these deposits.
Foreign Currency Risk
We have no operations outside the U.S. and do not hold any foreign currency denominated financial instruments.
Effects of Inflation
We do not believe that inflation and changing prices during the three months ended March 31, 2014 had a significant impact on our results of operations.
ITEM 4. CONTROLS AND PROCEDURES
Evaluation of Disclosure Controls and Procedures
We have performed an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) unde Securities Exchange Act of 1934 (the Exchange Act). Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of March 31, 2014 to provide reasonable assurance that information required to be disclosed by us in the reports

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Changes in Internal Control Over Financial Reporting
There was no change in our internal control over financial reporting during the quarter ended March 31, 2014 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.
PART II. OTHER INFORMATION
ITEM 1. LEGAL PROCEEDINGS
We are not a party to any pending legal proceeding, nor is our property the subject of a pending legal proceeding, that is not in the ordinary course of business or otherwise material to the financial condition of our business. None of our directors, officers or affiliates is involved in a proceeding adverse to our business or has a material interest adverse to our business.
ITEM 1A. RISK FACTORS
There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2013.
ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds
Not applicable.
ITEM 3. Default Upon Senior Securities
Not applicable.
ITEM 4. Mine Safety Disclosures

Not applicable.

#### ITEM 5. Other Information

On May 8, 2014, we entered into a Patent Assignment and License Agreement, effective as of April 23, 2014, with GenSignia IP Ltd. (GenSignia), a United Kingdom company, pursuant to which we assigned all of our miRNA patents, including methods of using miRNA for detection of in vivo cell death and detecting cell-free miRNA in urine and blood. Concurrent with the assignment, GenSignia granted to us an exclusive, world-wide, royalty-free, fully paid, perpetual license under the transferred patents in the urine field. Pursuant to the agreement, GenSignia will pay us a low single digit royalty on net sales and will pay an aggregate \$6.5 million in milestone payments upon the achievement of up to \$150 million in net sales. GenSignia shall be responsible for the preparation, filing and maintenance of all patents under the agreement. Antonius Schuh, our CEO and a director, is a director of GenSignia. Dr. Schuh did not participate in any negotiations with respect to the agreement and recused himself from any director vote in connection with the agreement.

#### **ITEM 6. EXHIBITS**

Exhibit Number	Description of Exhibit
10.1*	Patent Assignment and License Agreement between Trovagene, Inc. and Gensignia IP Ltd. effective as of April 23, 2014.
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2014 filed on May 12, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the Condensed Consolidated Financial Statements tagged as blocks of text.
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<sup>\*</sup>Portions of this exhibit were omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to a request for confidential treatment.

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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.

May 12, 2014 By: /s/ Antonius Schuh

Antonius Schuh Chief Executive Officer

TROVAGENE, INC.

May 12, 2014 By: /s/ Stephen Zaniboni

Stephen Zaniboni Chief Financial Officer

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