Trovagene, Inc.
Form 10-Q
November 09, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)
x QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016

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

For the transition period from to

COMMISSION FILE NUMBER 001-35558

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

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

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

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

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

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

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

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

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

As of October 31, 2016, the issuer had 30,615,406 shares of Common Stock issued and outstanding.

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TROVAGENE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$22,569,107	$67,493,047
Short-term investments	24,376,904	—
Accounts receivable	85,152	98,736
Prepaid expenses and other assets	946,388	789,285
Total current assets	47,977,551	68,381,068
Property and equipment, net	4,654,876	2,690,579
Other assets	371,243	374,004
Total Assets	$53,003,670	$71,445,651
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$925,173	$1,040,868
Accrued expenses	4,558,809	1,903,797
Deferred rent	279,710	30,614
Current portion of long-term debt	801,024	5,225,818
Total current liabilities	6,564,716	8,201,097
Long-term debt, less current portion	15,595,400	11,246,188
Derivative financial instruments - warrants	2,622,243	3,297,077
Deferred rent, net of current portion	1,446,912	—
Total Liabilities	26,229,271	22,744,362
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, $0.001 par value, 20,000,000 shares authorized; 60,600 shares outstanding at September 30, 2016 and December 31, 2015; designated as Series A Convertible Preferred Stock with liquidation preference of $606,000 at September 30, 2016 and December 31, 2015	60	60
Common stock, $0.0001 par value, 150,000,000 shares authorized; 30,599,140 and 29,737,601 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	3,060	2,974
Additional paid-in capital	166,337,512	157,585,498
Accumulated other comprehensive loss	(4,742)	—
Accumulated deficit	(139,561,491)	(108,887,243)
Total stockholders' equity	26,774,399	48,701,289
Total liabilities and stockholders' equity	$53,003,670	$71,445,651

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Royalties	$47,236	$51,301	$207,869	$222,931
Diagnostic services	37,978	6,026	69,558	10,712
Clinical research services	3,900	—	35,573	—
Total revenues	89,114	57,327	313,000	233,643
Costs and expenses:				
Cost of revenues	424,559	173,537	1,143,293	429,992
Research and development	3,937,398	2,546,533	11,221,876	7,428,349
Selling and marketing	2,940,862	1,798,263	9,127,450	4,508,766
General and administrative	2,710,782	1,948,546	9,183,761	5,756,047
Total operating expenses	10,013,601	6,466,879	30,676,380	18,123,154
Loss from operations	(9,924,487)	(6,409,552)	(30,363,380)	(17,889,511)
Net interest expense	(354,993)	(335,359)	(967,522)	(1,100,080)
Gain (loss) from change in fair value of derivative financial instruments — warrants	88,208	4,017,212	674,834	(1,105,270)
Other income (loss), net	—	(8,130)	—	4,617
Net loss	(10,191,272)	(2,735,829)	(30,656,068)	(20,090,244)
Preferred stock dividend	(6,060)	(6,060)	(18,180)	(18,180)
Net loss attributable to common stockholders	$(10,197,332)	$(2,741,889)	$(30,674,248)	$(20,108,424)
Net loss per common share — basic	$(0.34)	$(0.10)	$(1.02)	$(0.80)
Net loss per common share — diluted	$(0.34)	$(0.23)	$(1.04)	$(0.96)
Weighted average shares outstanding — basic	30,339,774	28,560,211	30,018,841	25,014,966
Weighted average shares outstanding — diluted	30,339,774	29,128,235	30,136,572	25,204,307

See accompanying notes to the unaudited condensed consolidated financial statements.

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TROVAGENE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$(10,191,272)	$(2,735,829)	$(30,656,068)	$(20,090,244)
Other comprehensive loss:				
Foreign currency translation loss	(81)	—	(1,877)	—
Unrealized loss on securities available-for-sale	(7,997)	—	(2,865)	—
Total other comprehensive loss	(8,078)	—	(4,742)	—
Total comprehensive loss	(10,199,350)	(2,735,829)	(30,660,810)	(20,090,244)
Preferred stock dividend	(6,060)	(6,060)	(18,180)	(18,180)
Comprehensive loss attributable to common stockholders	$(10,205,410)	$(2,741,889)	$(30,678,990)	$(20,108,424)

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

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	$(30,656,068)	$(20,090,244)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net gain on disposal of fixed assets	—	4,562
Depreciation and amortization	693,485	250,600
Stock based compensation expense	5,942,392	2,758,847
Accretion of final fee premium	266,423	253,028
Amortization of discount on debt	105,710	59,665
Amortization of premiums on short-term investments	61,719	—
Deferred rent	(133,378)	—
Interest income accrued on short-term investments	10,122	—
Change in fair value of derivative financial instruments - warrants	(674,834)	1,105,270
Changes in operating assets and liabilities:		
Decrease (increase) in other assets	2,761	(10,273)
Decrease (increase) in accounts receivable	13,584	(231,672)
Increase in prepaid expenses	(157,051)	(26,238)
Increase in accounts payable and accrued expenses	2,490,137	616,366
Net cash used in operating activities	(22,034,998)	(15,310,089)
Investing activities:		
Capital expenditures, net	(797,781)	(1,256,988)
Net purchases of short-term investments	(24,451,611)	—
Net cash used in investing activities	(25,249,392)	(1,256,988)
Financing activities:		
Proceeds from sales of common stock, net of expenses	2,293,857	61,215,398
Proceeds from exercise of options	366,966	818,251
Proceeds from exercise of warrants	—	1,389,427
Borrowings under equipment line of credit	792,251	—
Borrowings under long-term debt, net of costs	7,805,086	—
Repayments of long-term debt	(8,896,166)	—
Net cash provided by financing activities	2,361,994	63,423,076
Effect of exchange rate changes on cash and cash equivalents	(1,544)	—
Net change in cash and equivalents	(44,923,940)	46,855,999
Cash and cash equivalents—Beginning of period	67,493,047	27,293,798
Cash and cash equivalents—End of period	$22,569,107	$74,149,797
Supplementary disclosure of cash flow activity:		
Cash paid for taxes	$4,560	$800
Cash paid for interest	$806,228	$795,375
Supplemental disclosure of non-cash investing and financing activities:		
Preferred stock dividends accrued	$18,180	$18,180

Warrants issued in connection with Amendment to the Loan and Security Agreement	$148,885	$—
Reclassification of derivative financial instruments - warrants to additional paid in capital	$—	$435,365
Leasehold improvements paid for by lessor	$1,860,000	$—

See accompanying notes to the unaudited condensed consolidated financial statements.

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

1. Organization and Basis of Presentation

Business Organization and Overview

Trovagene, Inc. ("Trovagene" or the "Company") is a molecular diagnostics company headquartered in San Diego, California. The Company's primary focus is to leverage its cell-free DNA molecular diagnostic technology in cancer and other diseases. Trovagene's goal is to broadly commercialize its molecular diagnostic technology via direct sales as well as external license agreements and/or collaborations to democratize cancer care by establishing the best access for patient care. The Company's proprietary Precision Cancer Monitoring® ("PCM") platform measures circulating tumor DNA ("ctDNA") in urine and blood, enabling personalized patient care. The Company's PCM platform as well as urine and blood based tests, also known as liquid biopsies, have the potential to dramatically improve cancer care and usher in an era of precision oncology. Trovagene's tests are available to clinicians for the assessment of known driver mutations in lung, pancreatic, colorectal, neuroendocrine cancers, melanoma and histiocytic disorders. The Company's noninvasive technology provides for clinically actionable information through the detection of cancer mutations and the monitoring of changes in tumor dynamics before, during, and after treatment.

Basis of Presentation

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

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

Liquidity

Trovagene's condensed consolidated financial statements as of September 30, 2016 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. Based on current plans, the Company will be required to raise additional capital in 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.

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

significant dilution. Any 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

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•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 $44.4 million of cash, cash equivalents and short-term investments at October 31, 2016.

2. Summary of Significant Accounting Policies

Use of Estimates

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

Revenue Recognition

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

Milestone, Royalty and License Revenues

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

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

•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 condensed consolidated statements of operations under the caption "Gain (loss) from change in fair value of derivative financial instruments - warrants."

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, 2016, and December 31, 2015, the fair value of these warrants was $2,622,243 and

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$3,297,077, respectively, and are recorded as a liability under the caption "Derivative financial instruments - warrants" on the balance sheet.

Net Loss Per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Numerator: Net loss attributable to common shareholders	$(10,197,332)	$(2,741,889)	$(30,674,248)	$(20,108,424)
Adjustment for (gain) loss from change in fair value of derivative financial instruments - warrants	—	(4,017,212)	(533,750)	(4,017,212)
Net loss used for diluted loss per share	$(10,197,332)	$(6,759,101)	$(31,207,998)	$(24,125,636)
Denominator for basic and diluted net loss per share:				
Weighted average shares used to compute basic loss per share	30,339,774	28,560,211	30,018,841	25,014,966
Adjustments to reflect assumed exercise of warrants	—	568,024	117,731	189,341
Weighted average shares used to compute diluted net loss per share	30,339,774	29,128,235	30,136,572	25,204,307
Net loss per share attributable to common stockholders:				
Basic	$(0.34)	$(0.10)	$(1.02)	$(0.80)
Diluted	$(0.34)	$(0.23)	$(1.04)	$(0.96)

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,	
	2016	2015
Options to purchase Common Stock	6,051,186	6,514,130
Warrants to purchase Common Stock	4,546,939	4,565,947
Restricted Stock Units	392,000	—
Series A Convertible Preferred Stock	63,125	63,125
	11,053,250	11,143,202

Recent Accounting Pronouncements

In August 2016, the FASB issued Accounting Standards Update 2016-15, Classification of Certain Cash Receipts and Cash Payments (“ASU 2016-15”), which includes amendments that clarify how certain cash receipts and cash payments are presented in the statement of cash flows. ASU 2016-15 also provides guidance clarifying when an entity should separate cash receipts and cash payments and classify them into more than one class of cash flows. The new

amendments and guidance are effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted provided that all amendments are adopted in the same period. The Company is currently evaluating the impact of adoption of ASU 2016-15 on its consolidated statements of cash flows.

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

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

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

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, 2016 and December 31, 2015:

	Fair Value Measurements at September 30, 2016			
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market fund (1)	$19,841,032	$—	$ —	$19,841,032
Corporate debt securities (2)	—	15,887,439	—	15,887,439

Commercial paper (2)	—	8,489,465	—	8,489,465
Total Assets	$19,841,032	$24,376,904	$ —	$44,217,936
Liabilities:				
Derivative financial instruments - warrants	$—	$—	$ 2,622,243	$2,622,243
Total Liabilities	$—	$—	$ 2,622,243	$2,622,243

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

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

(2) Included in short-term investments 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, 2016:

Description	Balance at December 31, 2015	Unrealized Gain	Balance at September 30, 2016
Derivative financial instruments - warrants	$3,297,077	$(674,834)	$2,622,243

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

4. Investments

Investments consist of corporate debt securities and commercial paper. The Company classifies debt securities as available-for-sale, as the sale of such securities may be required prior to maturity to execute management strategies. Investments classified as available-for-sale are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders’ equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary will result in an impairment charge to earnings and a new cost basis for the security is established. No such impairment charges were recorded for any period presented. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method and included in interest income. Interest income is recognized when earned. Realized gains and losses on investments in securities will be included in other income (loss) within the condensed consolidated statements of operations. There were no realized gains and

losses for the nine months ended September 30, 2016.

The following table sets forth the composition of securities available-for-sale as of September 30, 2016.

	Maturity in Years	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	Less than 1 year	$15,890,304	$2,162	$(5,027)	$15,887,439
Commercial paper	Less than 1 year	8,489,465	—	—	8,489,465
Total Investment		$24,379,769	$2,162	$(5,027)	$24,376,904

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5. Property and Equipment

Property and equipment consist of the following:

	As of September 30, 2016	As of December 31, 2015
Furniture and office equipment	$1,727,321	$1,483,227
Leasehold improvements	1,994,514	39,401
Laboratory equipment	2,472,444	2,022,733
	6,194,279	3,545,361
Less—accumulated depreciation and amortization	(1,539,403)	(854,782)
Property and equipment, net	$4,654,876	$2,690,579

6. Debt

Equipment Line of Credit

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

The Company is also subject to certain affirmative and negative covenants under the Equipment Line of Credit. As of September 30, 2016, the Company was in compliance with all covenants.

As of September 30, 2016, $1,878,312 has been borrowed under the Equipment Line of Credit. As of September 30, 2016, amounts due under the Equipment Line of Credit included $573,929 in current liabilities and $1,328,355 in long-term liabilities, which includes $23,972 of final fee premium accretion. The Company recorded $80,176 in interest expense related to the Equipment Line of Credit during the nine months ended September 30, 2016.

Future principal payments of long-term debt at September 30, 2016 are as follows:

Year Ended December 31,	
2016	$104,351
2017	626,104
2018	626,104
2019	521,753
Total principal	1,878,312
Plus final fee premium accretion	23,972
Total long-term obligations	$1,902,284

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. 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.

On July 20, 2016, the Company signed the 5th Amendment to Loan and Security Agreement (“Amendment”) to refinance its existing term loan. Under the Amendment, interest is equal to 3.75% plus the Wall Street Journal Prime Rate,

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subject to a floor of 7.25%. The Company is required to make interest only payments on the outstanding amount of the loan on a monthly basis through September 1, 2017, after which equal monthly payments of principal and interest are due until the loan maturity date of February 1, 2020. In addition, the lenders received a warrant to purchase an aggregate 30,992 shares of the Company's common stock at an exercise price of $4.84 per share exercisable for ten years from the date of issuance. The fair value of the warrants, totaling $148,885, was recorded as debt discount and additional paid-in capital as the warrants were equity classified. As of September 30, 2016, warrants to purchase 73,727 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 Amendment, either in the event of repayment of the loan at maturity or upon any prepayment, the Company is obligated to pay the final fee of $1,125,000.

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, and is required to maintain its primary operating, deposit and securities accounts with the lender. In addition, 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, 2016.

As of September 30, 2016, amounts due under the Agreement include $227,095 in current liabilities, which include $272,905 of current portion of debt discount, and $14,267,045 in long-term liabilities, which include $76,575 of final fee premium accretion. The Company recorded $1,113,943 in interest expense related to the Agreement during the nine months ended September 30, 2016.

Future principal payments of long-term debt at September 30, 2016 are as follows:

Year Ended December 31,	
2016	$—
2017	2,000,000
2018	6,000,000
2019	6,000,000
2020	1,000,000
Total principal	15,000,000
Less discount	(582,435)
Plus final fee premium accretion	76,575
Total long-term obligations	$14,494,140

7. 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 condensed consolidated statements 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:

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	Nine Months Ended September 30,	
	2016	2015
Estimated fair value of Trovagene common stock	4.49-4.65	5.69-10.15
Expected warrant term	2.3-2.8 years	3.3-3.8 years
Risk-free interest rate	0.71-0.87%	0.89-1.01%
Expected volatility	82-90%	75-77%
Dividend yield	0 %	0 %

Expected volatility is based on historical volatility. 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 - warrants liability balance, valued using the Black-Scholes option pricing method, for the periods indicated.

Date	Description	Number of Warrants	Derivative Instrument Liability
December 31, 2015	Balance of derivative financial instruments - warrants liability	967,295	$3,297,077
	Change in fair value of derivative financial instruments - warrants during the period recognized as a gain in the condensed consolidated statements of operations	—	(674,834)
September 30, 2016	Balance of derivative financial instruments - warrants liability	967,295	$2,622,243

8. Stockholders' Equity

Common Stock

During the nine months ended September 30, 2016, the Company issued a total of 861,539 shares of Common Stock. The Company received gross proceeds of approximately $2.4 million from the sale of 421,810 shares of its common stock at a weighted average price of $5.61 under the agreement with Cantor Fitzgerald & Co. ("Agent"). In addition, 98,396 shares were issued upon exercise of options for a weighted average price of $3.73, and 341,333 shares were issued upon net exercise of 1,236,875 options at a weighted average exercise price of $3.81.

Stock Options

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Included in research and development expense	$872,792	$342,122	$1,862,069	$1,054,443
Included in cost of revenue	42,639	7,518	99,164	22,468
Included in selling and marketing expense	476,865	225,892	1,493,744	480,006

Included in general and administrative expense	437,075	348,127	2,487,415	1,201,929
Total stock-based compensation expense	$1,829,371	$923,659	$5,942,392	$2,758,846

The unrecognized compensation cost related to non-vested stock options outstanding at September 30, 2016 and 2015, net of expected forfeitures, was $10,416,565 and $10,308,131, 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, 2016 was approximately eight years.

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

	Nine Months Ended September 30,	
	2016	2015
Risk-free interest rate	1.48 %	1.77 %
Dividend yield	0 %	0 %
Expected volatility	103 %	76 %
Expected term	5.5 years	6.1 years

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

	Total Options	Weighted Average Exercise Price Per Share	Intrinsic Value
Balance outstanding, December 31, 2015	6,948,630	$ 5.45	$5,903,466
Granted	3,234,750	5.02	
Exercised	(1,335,271)	3.81	
Canceled / Forfeited	(2,690,146)	5.44	
Expired	(106,777)	11.14	
Balance outstanding, September 30, 2016	6,051,186	5.49	1,724,990
Exercisable at September 30, 2016	2,287,028	5.13	1,325,134

During the nine months ended September 30, 2016, the Company had issued 996,000 options to its executive officers and non-employee directors that were over the authorized number of shares available in the Trovagene 2014 Equity Incentive Plan (2014 EIP) and were subject to shareholder approval. As per ASC Topic 815-40, the options were accounted for as liabilities and recorded at fair value with the changes in fair value being recorded in the Company's condensed consolidated statements of operations. Stockholder approval was obtained on May 17, 2016 to increase the number of authorized shares in the 2014 EIP from 5,000,000 to 7,500,000. Accordingly, the options were remeasured as of the date of stockholder approval with the change recorded in stock based compensation expense and the $217,333 liability was reclassified to additional paid in capital. As of September 30, 2016 there were 2,346,478 shares available for issuance under the 2014 EIP.

Restricted Stock Units

Under guidance provided by ASC Topic 718 "Compensation—Stock Compensation" for share-based payments, the fair value of our restricted stock units is based on the grant date fair value of our common stock. All restricted stock units were granted with no purchase price. Vesting of the restricted stock units is generally subject to service conditions, while vesting of certain units are based on attainment of specific performance objectives. The weighted-average grant date fair value of the restricted stock units was $4.06 per share during the nine months ended September 30, 2016. There were no restricted stock units granted during the year ended December 31, 2015.

A summary of the restricted stock unit activity is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value

		Per Share	
Non-vested restricted stock units outstanding, December 31, 2015	—	$	—
Granted	402,000	4.06	
Forfeited	(10,000)	3.99	
Non-vested restricted stock units outstanding, September 30, 2016	392,000	4.06	

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None of the restricted stock units vested during the nine months ended September 30, 2016. At September 30, 2016, total unrecognized compensation cost related to non-vested restricted stock units was $537,134, which is expected to be recognized over a weighted-average period of three months.

Warrants

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

	Total Warrants	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2015	5,533,242	$ 3.86	2.50
Granted	30,992	4.84	
Expired	(50,000)	8.00	
Balance outstanding, September 30, 2016	5,514,234	3.82	1.85

9. Commitments and Contingencies

Executive and Consulting Agreements

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

Lease Agreements

The Company previously leased approximately 22,600 square feet of office and laboratory space at a monthly rental rate of approximately $60,000. On April 4, 2016, the Company entered into an amendment to the lease agreement which expanded the square footage of its office space to approximately 26,100 square feet at a revised monthly rental rate of approximately $68,000. Under the amendment, the lessor provided the Company with a $1,860,000 tenant improvement allowance which the Company recorded as a deferred rent obligation. The Company will amortize the deferred rent on a straight-line basis over the life of the lease. The new lease will expire on December 31, 2021. The Company also leases certain lab and office space in Torino, Italy, of approximately 2,300 square feet, at a monthly rental rate of approximately $3,100. The lease is for a period of three years and expires December 31, 2018.

Research and Development Agreements

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. Included in research and development expense, the Company has recorded approximately $0.8 million for the nine months ended September 30, 2016 relating to services provided by the collaborators in connection with these agreements.

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

The Company has entered into a collaborative research program under which it will work to design and validate custom enrichment panels--as specified by the Company. The research partner will be reimbursed for a portion of incurred costs, plus a fixed fee for target services performed. The research agreement includes an outline for a

provisional commercial agreement that provides the Company with an exclusive license to use the research partner's technology in exchange for two milestone payments. The commercial agreement has not been finalized as of September 30, 2016.

Public Offering and Controlled Equity Offering

On May 27, 2016 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, debt securities, warrants, or units having an aggregate initial offering price not exceeding $250,000,000. The preferred stock, debt securities, 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 June 13,

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2016. The Company had 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. Gross proceeds of $2.4 million have been raised since the date of effectiveness of the Form S-3 on June 13, 2016.

Database Usage

In March 2016 the Company entered into an agreement with an outside vendor to develop an online database for test requisition and test results. Under the agreement, the Company is obligated to pay a fixed development fee, and a usage fee each time an external user completes and submits a test order form to the database. To date, the Company has paid the fixed development fee, but has incurred no costs in connection with the usage fees.

Other Matters

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

10. Related Party Transactions

In March 2016, the Company engaged Rutan & Tucker, LLP, a law firm to represent Trovagene, Inc. with respect to various lawsuits. One of the partners from Rutan & Tucker, LLP, is the son of the Company's Chairman of the Board. The fees for legal services are based on the hourly rates of the individuals performing the legal services. As of September 30, 2016, the Company has incurred approximately $376,000 of legal expenses for services performed by Rutan & Tucker, LLP.

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 $743,000 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, 2016, the Company has incurred and recorded approximately $555,000 of research and development expenses related to the agreement. No royalty expense has been incurred as of September 30, 2016.

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

Forward-Looking Statements

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

projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions.

In addition, our business and financial performance may be affected by the factors that are discussed under “Risk Factors” in the Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 10, 2016, and on Form 10-Q for the periods ended June 30, 2016, filed on August 4, 2016. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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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 diagnostics company that focuses on the development and commercialization of both proprietary urine and blood-based cell-free molecular diagnostic technologies for use in the detection and monitoring of cancer mutations 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, urology transplantation, and prenatal genetics. Our current goal is to improve treatment outcomes for cancer patients using our proprietary technology to detect and quantitatively monitor cell-free DNA in urine and/or blood.

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

Our fundamental ctDNA diagnostic platform, also known as Precision Cancer Monitoring®, ("PCM") 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, noninvasive 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, 2016, our intellectual property portfolio consists of 101 issued patents worldwide and over 70 pending patent applications globally. Our patent estate includes intellectual property for the detection of cell-free nucleic acids that pass through the kidney into the urine, as well as their application in specific disease areas, including oncology, infectious disease, transplantation, urology, and prenatal genetics.

We believe that our proprietary PCM platform is uniquely positioned to address a high unmet clinical need in the 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, noninvasive monitoring of cancer 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 a 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 ("PCR"). We believe that our quantitative ctDNA detection and monitoring platform offers industry-leading sensitivity, featuring single nucleic acid molecule detection.

Our PCM platform is poised to overcome a significant clinical dilemma in the area of cancer treatment. Recent scientific evidence supports the molecular basis of cancer, and has resulted in a paradigm shift in the way cancer is treated. Researchers and clinicians are now focused on specific mutations that are believed to be the molecular drivers of cancer, and, as

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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' tumor, including a given patient’s response to treatments that are designed to target driver cancer mutations. Current monitoring tools such as imaging procedures, tissue biopsy, and circulating tumor cells are insufficient to meet the challenge of monitoring cancer 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 cancer 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 noninvasive, 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, 2016 is $139,561,491. To date, we have generated minimal revenues and expect to incur additional losses to perform further research and development activities and expand commercial operations. During 2016, we have advanced our business with the following activities:

- Entered into preferred provider agreements with Blue Cross Blue Shield Illinois, Stratose, Inc., Multiplan, Inc., Three Rivers Provider Network, Fortified Provider Network, FedMed, Inc., American’s Choice Provider Network, and Galaxy Health Network. These combined agreements represent in-network coverage for approximately 168 million covered lives.

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

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

- Presented clinical study results for our Trovera™ ctDNA tests at the 2016 ASCO Annual Meeting. Results demonstrated highly sensitive detection of EGFR T790M mutations and validated urine ctDNA testing as an alternative to tissue and plasma.

- Entered into a clinical collaboration with the University of Michigan for monitoring and early detection of pancreatic cancer utilizing the Trovera™ KRAS ctDNA liquid biopsy test.

- Entered into a clinical collaboration with the USC Norris Comprehensive Cancer Center to standardize the use of Trovera™ ctDNA liquid biopsy test in patient care.

Published study results in the Journal of Thoracic Oncology that demonstrate the clinical and analytical validity of the Trovera™ urine and blood-based liquid biopsy tests to assess EGFR T790M mutational status. The data shows that the Trovera™ test successfully identifies EGFR mutations, and has high concordance with tumor tissue.

- Presented clinical study results for our Trovera™ tests at the 3rd Annual Precision Medicine Congress. The presentation highlighted Trovera's™ clinical utility in identifying driver mutations as well as the potential benefits of liquid biopsies, including: patient response to therapy, progression monitoring, and early detection.

- Entered into a partnership with the Pancreatic Cancer Action Network (PanCAN) to be the liquid biopsy provider for Precision Promise--the first large-scale precision medicine trial designed to transform care and treatment for patients with pancreatic cancer.

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- Published study results in Experimental Hematology & Oncology that illustrates the clinical utility of using Trovera™ urine liquid biopsy to confirm the presence of EGFR T790M mutational status in a patient with late-stage non-small cell lung cancer. The study concluded that ctDNA analysis should be considered a valuable diagnostic tool in treatment decision-making.

- Invited to present four abstracts at the International Association for the Study of Lung Cancer's (IASLC) 17th World Conference on Lung Cancer. The presentation will focus on the clinical utility of Trovera™ in detection and monitoring of the EGFR T790M resistance mutation in non-small cell lung cancer. The presentation will also include first health outcomes and a total cost of care analysis, demonstrating that a urine-testing strategy shows improved cost-savings and patients' experiences compared to a tissue-testing strategy.

- Invited to present at the 31st International Papillomavirus Conference. Two abstracts will be presented. The first demonstrates clinical performance of urine and cervical samples in a Chinese screening population. These results support the utility of urine testing for cervical cancer screening among this population. The second abstract describes the analytical performance of the Trovagene HPV-UR urine test.

Our product development and commercialization efforts are in their early stages, and we cannot make estimates of the costs or the time that 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, 2016.

Critical Accounting Policies

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

RESULTS OF OPERATIONS

Three Months Ended September 30, 2016 and 2015

Revenues

Our total revenues were $89,114 and $57,327 for the three months ended September 30, 2016 and 2015, respectively. The components of our revenues were as follows:

	Three Months Ended September 30,	
	2016	2015

			Increase (Decrease)
Royalties	$47,236	$51,301	$ (4,065)
Diagnostic services	37,978	6,026	31,952
Clinical research services	$3,900	$—	3,900
Total revenues	$89,114	$57,327	$ 31,787

Revenue from diagnostic services is recognized when payment is received for the test results. The number of tests billed and payments received were higher in 2016 as compared to the same period in the prior year. Revenue from clinical research services consists primarily of revenue from the sale of urine and blood collection supplies under agreements with our

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clinical research and business development partners. Revenue was recognized when supplies were delivered. There was no such revenue for the three months ended September 30, 2015.

We expect our royalties 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 revenue from diagnostic services to increase in future periods, but as the revenue recognition is based on cash receipts, the timing of these revenues is also uncertain. We expect revenue from clinical research services to fluctuate based on timing of delivery of supplies under agreements.

Cost of Revenues

Our total cost of revenues was $424,559 for the three months ended September 30, 2016, compared to $173,537 in the same period of 2015. Cost of revenues mainly 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. Increase in cost of revenues for the three months ended September 30, 2016 compared to the same period of last year is mainly due to the increased volume of tests processed offset by decreased average cost per test.

Research and Development Expenses

Research and development expenses consisted of the following:

	Three Months Ended September 30,		
	2016	2015	Increase (Decrease)
Salaries and staff costs	$1,407,529	$1,037,831	$369,698
Stock-based compensation	872,792	342,122	530,670
Outside services, consultants and lab supplies	1,215,889	901,662	314,227
Facilities	372,891	193,926	178,965
Travel and scientific conferences	51,203	52,684	(1,481)
Other	17,094	18,308	(1,214)
Total research and development	$3,937,398	$2,546,533	$1,390,865

Research and development expenses increased by $1,390,865 to $3,937,398 for the three months ended September 30, 2016 from $2,546,533 for the same period in 2015. Our costs have increased mainly as a result of our internal research and development personnel increasing from twenty-seven to thirty-four and the use of additional consulting and outside services. We utilize clinical studies to provide data that supports our technology for the monitoring of responsiveness to therapy and the status of diseases. The number of samples processed in connection with our research and development clinical studies increased for the three months ended September 30, 2016 as compared to the same period in 2015. We expect research and development expenses to increase as we enter into additional collaborations, and complete the development of our urine collection and DNA extraction kits and multi-plex panels.

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Selling and Marketing Expenses

Selling and marketing expenses consisted of the following:

	Three Months Ended September 30,		
	2016	2015	Increase (Decrease)
Salaries and staff costs	$1,427,254	$681,421	$745,833
Stock-based compensation	476,865	225,892	250,973
Outside services and consultants	441,699	218,582	223,117
Facilities	112,573	70,665	41,908
Trade shows, conferences and marketing	243,692	432,123	(188,431)
Travel	212,375	157,163	55,212
Other	26,404	12,417	13,987
Total sales and marketing	$2,940,862	$1,798,263	$1,142,599

Selling and marketing expenses increased by $1,142,599 to $2,940,862 for the three months ended September 30, 2016 from $1,798,263 for the same period in 2015. During the three months ended September 30, 2016 we increased the number of our field sales, customer support and marketing personnel, bringing our average headcount to twenty-two from fourteen in the same period of the prior year. These additions to our commercial team support our sales and marketing activities, resulting in the increase in salaries and staff costs and stock-based compensation. The increase in outside services and consultants is due to our utilization of outside marketing consultants and agents for targeted marketing activities such as website design, product branding and printing services. We expect our selling and marketing expenses to change based on the composition of commercial team members that are focused on increasing market acceptance of our commercially available tests and the commercial introduction of future product offerings, such as our urine collection and DNA extraction kits.

General and Administrative Expenses

General and administrative expenses consisted of the following:

	Three Months Ended September 30,		
	2016	2015	Increase (Decrease)
Personnel and outside services costs	$1,136,266	$879,722	$256,544
Board of Directors' fees	122,187	108,612	13,575
Stock-based compensation	437,075	348,127	88,948
Legal and accounting fees	695,061	286,312	408,749
Facilities and insurance	149,921	152,714	(2,793)
Travel	47,769	97,106	(49,337)
Fees, licenses, taxes and other	122,503	75,953	46,550
Total general and administrative	$2,710,782	$1,948,546	$762,236

General and administrative expenses increased by $762,236 to $2,710,782 for the three months ended September 30, 2016, from $1,948,546 for the same period in 2015. The overall increase was primarily due to the increase of personnel and outside services costs and 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 to support our overall headcount growth. The increase in legal and accounting fees primarily resulted from the lawsuit against the Company's

former CEO and CFO. Stock-based compensation, a non-cash expense, will fluctuate based on the timing and amount of options granted, forfeitures and the fair value of the options at the time of grant or remeasurement. We expect our general and administrative costs to increase as our commercial operations and research and development teams grow and if we need to retain additional legal resources.

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Net interest Expense

Net interest expense was $354,993 and $335,359 for the three months ended September 30, 2016 and 2015, respectively. The increase of net interest expense is primarily due to an increase in interest expense, offset by an increase in interest income of approximately $62,000. This increase is due to the investment of a portion of our cash and cash equivalents in short-term investments which have a higher average yield as well as overall higher average cash and investment balances during the three months ended September 30, 2016 as compared to the same period of the prior year. We expect net interest expense to increase as a result of our debt refinancing and as our average cash and investment balances decrease.

Change in Fair Value of Derivative Financial Instruments - Warrants

We have issued warrants that are accounted for as derivative liabilities. As of September 30, 2016, the derivative financial instruments - warrants liabilities were revalued to $2,622,243, resulting in a decrease in value of $88,208 from June 30, 2016, based primarily upon the decrease in our stock price from $4.53 at June 30, 2016 to $4.49 at September 30, 2016 as well as the changes in the expected term and risk free interest rates for the expected term. The decrease in value was recorded as a gain from the change in fair value of derivative financial instruments - warrants in the condensed consolidated statement of operations.

Net Loss

Net loss and per share amounts were as follows:

	Three Months Ended September 30,		
	2016	2015	Increase
Net loss attributable to common shareholders	$(10,197,332)	$(2,741,889)	$7,455,443
Net loss per common share — basic	$(0.34)	$(0.10)	$0.24
Net loss per common share — diluted	$(0.34)	$(0.23)	$0.11
Weighted average shares outstanding — basic	30,339,774	28,560,211	1,779,563
Weighted average shares outstanding — diluted	30,339,774	29,128,235	1,211,539

The $7,455,443 increase in net loss attributable to common shareholders and the $0.24 increase in basic net loss per share was primarily the result of an increase in operating expenses of $3,546,722, and a decrease in gain from the change in fair value of derivative financial instruments - warrants of $3,929,004 for the nine months ended September 30, 2016 compared to the same period in the prior year.

Nine Months Ended September 30, 2016 and 2015

Revenues

Our total revenues were $313,000 and $233,643 for the nine months ended September 30, 2016 and 2015, respectively. The components of our revenues were as follows:

	Nine Months Ended September 30,		
	2016	2015	Increase (Decrease)
Royalties	$207,869	$222,931	$ (15,062)
Diagnostic services	69,558	10,712	58,846
Clinical research services	35,573	—	35,573

Total revenues	$313,000	$233,643	$ 79,357

The $15,062 decrease in royalties related primarily to lower receipts of payments in excess of minimum royalties in comparison to the same period of the prior year. Revenue from diagnostic services is recognized when payment is received for the test results. The number of tests billed and payments received were higher for the nine months ended September 30, 2016 as compared to the same period in the prior year. Revenue from clinical research services consists primarily of revenue from the sale of urine and blood collection supplies under agreements with our clinical research and business development partners.

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Revenue was recognized when supplies were delivered. There was no such revenue for the nine months ended September 30, 2015.

We expect our royalties 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. We expect our revenue from diagnostic services to increase in future periods, but as the revenue recognition is based on cash receipts, the timing of these revenues is also uncertain. In addition, we expect revenue from clinical research services to fluctuate based on timing of delivery of supplies under agreements.

Cost of Revenues

Our total cost of revenues was $1,143,293 for the nine months ended September 30, 2016, compared to $429,992 in the same period of 2015. 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. Increase in cost of revenues for the nine months ended September 30, 2016 compared to the same period of last year is mainly due to the increased volume of test processed offset by decreased average cost per test.

Research and Development Expenses

Research and development expenses consisted of the following:

	Nine Months Ended September 30,		
	2016	2015	Increase
Salaries and staff costs	$4,263,595	$2,679,951	$1,583,644
Stock-based compensation	1,862,069	1,054,443	807,626
Outside services, consultants and lab supplies	3,837,485	2,955,738	881,747
Facilities	1,042,682	552,259	490,423
Travel and scientific conferences	157,445	148,766	8,679
Other	58,600	37,192	21,408
Total research and development	$11,221,876	$7,428,349	$3,793,527

Research and development expenses increased by $3,793,527 to $11,221,876 for the nine months ended September 30, 2016 from $7,428,349 for the same period in 2015. Our costs have increased primarily due to the average number of our internal research and development personnel growing from twenty to thirty-three. In addition, we purchased additional lab supplies and clinical samples to support the number of samples processed and validated in connection with our research and development clinical studies as well as the development of our urine collection and DNA extraction kits. We utilize clinical studies to provide data that supports our technology for the monitoring of responsiveness to therapy and the status of diseases. The number of samples processed in connection with our research and development clinical studies increased for the nine months ended September 30, 2016 as compared to the same period in 2015. We expect research and development expenses to increase as we enter into additional collaborations or studies and complete the development of our urine collection and DNA extraction kits and multi-plex panels.

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Selling and Marketing Expenses

Selling and marketing expenses consisted of the following:

	Nine Months Ended September 30,		
	2016	2015	Increase
Salaries and staff costs	$4,266,029	$1,758,789	$2,507,240
Stock-based compensation	1,493,744	480,006	1,013,738
Outside services and consultants	1,117,368	654,512	462,856
Facilities	362,339	210,153	152,186
Trade shows, conferences and marketing	1,082,883	1,005,859	77,024
Travel	716,473	330,399	386,074
Other	88,614	69,048	19,566
Total sales and marketing	$9,127,450	$4,508,766	$4,618,684

Selling and marketing expenses increased by $4,618,684 to $9,127,450 for the nine months ended September 30, 2016 from $4,508,766 for the same period in 2015. During the nine months ended September 30, 2016 we increased the number of our field sales, customer support and marketing personnel, bringing our average headcount to twenty-two from eleven in the same period of the prior year. We also increased utilization of outside marketing consultants and agents for targeted marketing activities such as social media engagements and website design services.

General and Administrative Expenses

General and administrative expenses consisted of the following:

	Nine Months Ended September 30,		
	2016	2015	Increase (Decrease)
Personnel and outside services costs	$3,279,860	$2,582,108	$697,752
Board of Directors' fees	345,240	339,823	5,417
Stock-based compensation	2,487,415	1,201,929	1,285,486
Legal and accounting fees	2,077,585	855,101	1,222,484
Facilities and insurance	551,382	366,109	185,273
Travel	151,355	206,741	(55,386)
Fees, licenses, taxes and other	290,924	204,236	86,688
Total general and administrative	$9,183,761	$5,756,047	$3,427,714

General and administrative expenses increased by $3,427,714 to $9,183,761 for the nine months ended September 30, 2016, from $5,756,047 for the same period in 2015. The significant components of the increase were primarily due to the increase of personnel and outside services costs, stock-based compensation and legal fees. The increase of personnel and outside services costs is due to an increase in average headcount from six to eleven 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 to support our overall headcount growth. In January 2016, our former CEO was granted a non-qualified stock option to purchase 350,000 shares of Common Stock at an exercise price of $5.18 per share. As the stock option was vested upon grant, the fair value of the option, which approximated $1.2 million was expensed in full during the nine months ended September 30, 2016. Legal fees increased primarily as a result of a lawsuit against the Company's former CEO and CFO, and review of federal and state tax regulations with respect to certain executive compensation.

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Net Interest Expense

Net interest expense was $967,522 and $1,100,080 for nine months ended September 30, 2016 and 2015, respectively. The decrease of net interest expense is primarily due to an increase in interest income of approximately $193,518, resulting from the investment of a portion of our cash and cash equivalents in short-term investments which have a higher average yield as well as overall higher average cash and investment balances during the nine months ended September 30, 2016 as compared to the same period of the prior year.

Change in Fair Value of Derivative Financial Instruments - Warrants

We have issued warrants that are accounted for as derivative liabilities. As of September 30, 2016, the derivative financial instruments - warrants liabilities were revalued to $2,622,243, resulting in a decrease in value of $674,834 from December 31, 2015, based primarily upon the decrease in our stock price from $5.40 at December 31, 2015 to $4.49 at September 30, 2016 as well as the changes in the expected term and risk free interest rates for the expected term. The decrease in value was recorded as a gain from the change in fair value of derivative financial instruments - warrants in the condensed consolidated statement of operations.

Net Loss

Net loss and per share amounts were as follows:

	Nine Months Ended September 30,		
	2016	2015	Increase
Net loss attributable to common shareholders	$(30,674,248)	$(20,108,424)	$10,565,824
Net loss per common share — basic	$(1.02)	$(0.80)	$0.22
Net loss per common share — diluted	$(1.04)	$(0.96)	$0.08
Weighted average shares outstanding — basic	30,018,841	25,014,966	5,003,875
Weighted average shares outstanding — diluted	30,136,572	25,204,307	4,932,265

The $10,565,824 increase in net loss attributable to common shareholders and the $0.22 increase in basic net loss per share was primarily the result of an increase in operating expenses of $12,553,226 compared to the same period in the prior year. This increase was offset by a $674,834 gain from the change in the fair value of derivative financial instruments - warrants for the nine months ended September 30, 2016, as compared to a loss from the change in the fair value of derivative financial instruments - warrants of $1,105,270 for the same period in the prior year.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2016, we had $22,569,107 in cash and cash equivalents. Net cash used in operating activities for the nine months ended September 30, 2016 was $22,034,998, compared to $15,310,089 for the nine months ended September 30, 2015. Our use of cash was primarily a result of the net loss of $30,656,068 for the nine months ended September 30, 2016, adjusted for non-cash items related to stock-based compensation of $5,942,392, accretion of final fee premium of $266,423, amortization of discount on debt of $105,710, depreciation and amortization of $693,485, amortization of premiums on short-term investments of $61,719, deferred rent of $133,378, interest income accrued on short-term investments of $10,122, and the gain from the change in fair value of derivative financial instruments - warrants of $674,834. The changes in our operating assets and liabilities consisted of higher accounts payable and accrued expenses, an increase in prepaid expenses, and a decrease in accounts receivable and other assets. At our current and anticipated level of operating loss, we expect to continue to incur an operating cash outflow for the next several years.

Net cash used in investing activities was $25,249,392 during the nine months ended September 30, 2016, compared to $1,256,988 for the same period in 2015. Investing activities consisted of net purchases for capital equipment that used $797,781 in cash, and net purchase of short-term investments of $24,451,611.

Net cash provided by financing activities was $2,361,994 during the nine months ended September 30, 2016, compared to $63,423,076 for the same period in 2015. Financing activities during the nine months ended September 30, 2016 related primarily to the sale of our common stock through a controlled equity offering and net payment of long-term debt offset by

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borrowings under equipment line of credit. Financing activities during the same period of the prior year consisted primarily of proceeds from the sale of our common stock in underwritten public offerings.

As of September 30, 2016, and December 31, 2015, we had working capital of $41,412,835 and $60,179,971, respectively. As of October 31, 2016, our working capital was $52.3 million.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of our research and development programs and ramp up of our sales and marketing function. We will be required to raise additional capital during 2017 to complete the development and commercialization of current product candidates, to fund the potential 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 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.

CONTRACTUAL OBLIGATIONS

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our primary exposure to market risk due to changes in interest rates relates to the increase or decrease in the value of debt securities in our short-term investment portfolio and investments in short-term money marketable funds, as well as interest expense under our equipment line of credit.

Due to the short-term duration of our investment portfolio and the relatively low risk profile of our investments, a sudden change in interest rates would not have a material effect on the fair market value of our portfolio, nor our operating results or cash flows.

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

Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk, and reinvestment risk. We mitigate default risk by investing in investment grade securities. Changes in interest rates over time will increase or decrease our interest income.

Borrowings under the Company's equipment line of credit bear interest at floating rates. Changes in interest rates could affect the amounts of interest that we pay in the future.

Foreign Currency Risk

Our foreign currency exchange risk arises from our operations in Italy. Our functional and reporting currency is the United States dollar. We translate our foreign operations' assets and liabilities denominated in foreign currencies into U.S. dollars at current rates of exchange as of the balance sheet date and income and expense items at the average exchange rate for the reporting period. Translation adjustments resulting from exchange rate fluctuations are recorded in the cumulative

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translation account, a component of accumulated other comprehensive income. Gains or losses from foreign currency transactions are included in other expense (income), net.

Effects of Inflation

We do not believe that inflation and changing prices during the nine months ended September 30, 2016 had a significant impact on our results of operations.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We have performed an evaluation under the supervision and with the participation of our management, including our principal executive and financial officer, of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”). Based on that evaluation, our CEO and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2016 to provide reasonable assurance that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

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

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the three months ended September 30, 2016 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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

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, 2015, and Form 10-Q for the periods ended June 30, 2016.

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ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit
31.1	Certification of Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2016 filed on November 9, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the Condensed Consolidated Financial Statements tagged as blocks of text.

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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, 2016 By: /s/ William Welch
William Welch
Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)