

Trovogene, Inc.  
Form 10-Q  
August 04, 2016  
Table of Contents

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

OR

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

For the transition period from                      to

COMMISSION FILE NUMBER 001-35558

TROVAGENE, INC.

(Exact Name of registrant as specified in its charter)

Delaware                      27-2004382

(State or other jurisdiction of      (I.R.S. Employer  
incorporation or organization) 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 ☒ No ☐

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

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

As of July 31, 2016, the issuer had 30,147,514 shares of Common Stock issued and outstanding.

---

Table of Contents

TROVAGENE, INC.

Table of Contents

	Page
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1: Financial Statements (unaudited)</u>	
<u>Condensed Consolidated Balance Sheets (unaudited) as of June 30, 2016 and December 31, 2015</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2016 and 2015</u>	<u>4</u>
<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and six months ended June 30, 2016 and 2015</u>	<u>5</u>
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2016 and 2015</u>	<u>6</u>
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>7</u>
<u>Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>17</u>
<u>Item 3: Quantitative and Qualitative Disclosures About Market Risk</u>	<u>26</u>
<u>Item 4: Controls and Procedures</u>	<u>27</u>
<u>PART II OTHER INFORMATION</u>	
<u>Item 6: Exhibits</u>	<u>29</u>
<u>SIGNATURES</u>	

Table of Contents

TROVAGENE, INC.  
 CONDENSED CONSOLIDATED BALANCE SHEETS  
 (Unaudited)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$22,578,980	\$67,493,047
Short-term investments	28,004,561	—
Accounts receivable	158,537	98,736
Prepaid expenses and other assets	877,853	789,285
Total current assets	51,619,931	68,381,068
Property and equipment, net	4,731,738	2,690,579
Other assets	371,243	374,004
Total Assets	\$56,722,912	\$71,445,651
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$1,115,340	\$1,040,868
Accrued expenses	3,627,005	1,934,411
Current portion of long-term debt	6,146,744	5,225,818
Total current liabilities	10,889,089	8,201,097
Long-term debt, less current portion	9,031,389	11,246,188
Derivative financial instruments	2,710,451	3,297,077
Other liabilities	1,519,109	—
Total Liabilities	24,150,038	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 June 30, 2016 and December 31, 2015; designated as Series A Convertible Preferred Stock with liquidation preference of \$606,000 at June 30, 2016 and December 31, 2015	60	60
Common stock, \$0.0001 par value, 150,000,000 shares authorized; 30,147,305 and 29,737,601 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	3,015	2,974
Additional paid-in capital	161,930,622	157,585,498
Accumulated other comprehensive income	3,336	—
Accumulated deficit	(129,364,159)	(108,887,243)
Total stockholders' equity	32,572,874	48,701,289
Total liabilities and stockholders' equity	\$56,722,912	\$71,445,651

See accompanying notes to the unaudited condensed consolidated financial statements.



Table of Contents

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Royalties	\$47,765	\$46,826	\$160,633	\$171,630
Diagnostic services	23,962	2,520	31,580	4,686
Clinical research services	31,673	—	31,673	—
Total revenues	103,400	49,346	223,886	176,316
Costs and expenses:				
Cost of revenues	409,463	80,030	718,734	256,455
Research and development	4,076,414	2,684,157	7,284,478	4,881,816
Selling and marketing	3,129,036	1,915,850	6,186,588	2,710,503
General and administrative	2,468,732	2,001,516	6,472,979	3,807,501
Total operating expenses	10,083,645	6,681,553	20,662,779	11,656,275
Loss from operations	(9,980,245 )	(6,632,207 )	(20,438,893 )	(11,479,959 )
Net interest expense	(274,909 )	(381,252 )	(612,529 )	(764,721 )
Gain (loss) from change in fair value of derivative instruments — warrants	52,876	(3,175,754 )	586,626	(5,122,482 )
Other income (loss), net	—	9,179	—	12,747
Net loss and comprehensive loss	(10,202,278 )	(10,180,034 )	(20,464,796 )	(17,354,415 )
Preferred stock dividend	(6,060 )	(6,060 )	(12,120 )	(12,120 )
Net loss and comprehensive loss attributable to common stockholders	\$(10,208,338 )	\$(10,186,094 )	\$(20,476,916 )	\$(17,366,535 )
Net loss per common share — basic	\$(0.34 )	\$(0.41 )	\$(0.69 )	\$(0.75 )
Net loss per common share — diluted	\$(0.34 )	\$(0.41 )	\$(0.70 )	\$(0.75 )
Weighted average shares outstanding — basic	29,958,037	24,592,883	29,856,611	23,212,963
Weighted average shares outstanding — diluted	29,958,037	24,592,883	30,033,207	23,212,963

See accompanying notes to the unaudited condensed consolidated financial statements.

## Table of Contents

## TROVAGENE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended June 30, 2016		Six Months Ended June 30, 2015	
Net loss	\$(10,202,278)	\$(10,180,034)	\$(20,464,796)	\$(17,354,415)
Other comprehensive income (loss):				
Foreign currency translation loss	(1,145)	) —	(1,796)	) —
Unrealized gain on securities available-for-sale	5,132	—	5,132	—
Total other comprehensive income	3,987	—	3,336	—
Total comprehensive loss	(10,198,291 )	(10,180,034 )	(20,461,460 )	(17,354,415 )
Preferred stock dividend	(6,060 )	(6,060 )	(12,120 )	(12,120 )
Comprehensive loss attributable to common stockholders	\$(10,204,351)	\$(10,186,094)	\$(20,473,580)	\$(17,366,535)

Table of Contents

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

	Six Months Ended June 30,	
	2016	2015
Operating activities		
Net loss	\$(20,464,796)	\$(17,354,415)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net gain on disposal of fixed assets	—	(3,568 )
Depreciation and amortization	489,708	152,979
Stock based compensation expense	4,113,021	1,835,187
Amortization of debt costs	181,318	193,066
Accretion of discount on debt	52,641	57,026
Amortization of premiums on short-term investments	27,481	—
Deferred rent	(66,689 )	—
Interest income accrued on short-term investments	(75,300 )	—
Change in fair value of derivative instruments - warrants	(586,626 )	5,122,482
Changes in operating assets and liabilities:		
(Increase) decrease in other assets	2,761	(26,238 )
Increase in accounts receivable	(59,801 )	(43,023 )
Increase in prepaid expenses	(88,678 )	(139,149 )
Increase in accounts payable and accrued expenses	1,481,532	28,234
Net cash used in operating activities	(14,993,428 )	(10,177,419 )
Investing activities:		
Capital expenditures, net	(670,867 )	(687,965 )
Purchase of short-term investments	(27,951,611 )	—
Net cash used in investing activities	(28,622,478 )	(687,965 )
Financing activities:		
Proceeds from sales of common stock, net of expenses	—	23,816,292
Proceeds from exercise of options	232,144	564,051
Proceeds from exercise of warrants	—	485,027
Borrowings under equipment line of credit	792,251	—
Repayments of long-term debt	(2,320,083 )	—
Net cash (used in) provided by financing activities	(1,295,688 )	24,865,370
Effect of exchange rate changes on cash and cash equivalents	(2,473 )	—
Net change in cash and equivalents	(44,914,067 )	13,999,986
Cash and cash equivalents—Beginning of period	67,493,047	27,293,798
Cash and cash equivalents—End of period	\$22,578,980	\$41,293,784
Supplementary disclosure of cash flow activity:		
Cash paid for taxes	\$4,560	\$800
Cash paid for interest	\$536,727	\$530,250
Supplemental disclosure of non-cash investing and financing activities:		
Preferred stock dividends accrued	\$12,120	\$12,120
Reclassification of derivative financial instruments to additional paid in capital	\$—	\$435,365



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

Leasehold improvements paid for by lessor	\$1,860,000	\$—
---	-------------	-----

See accompanying notes to the unaudited condensed consolidated financial statements.

Table of Contents

TROVAGENE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Organization and Basis of Presentation

Business Organization and Overview

Trovogene, Inc. (“Trovogene” or the “Company”) is a molecular diagnostics company headquartered in San Diego, California. The Company’s primary focus is to leverage our cell-free DNA molecular diagnostic technology in cancer and other diseases. 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. Trovogene’s urine and blood based 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 allows for the detection of cancer mutations and the monitoring of changes in tumor dynamics before, during, and after treatment, providing clinically actionable information. Trovogene’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.

Basis of Presentation

The accompanying consolidated financial statements of Trovogene, which include its wholly owned subsidiary, Trovogene, 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

Trovogene’s condensed consolidated financial statements as of June 30, 2016 have been prepared under the assumption that Trovogene will continue as a going concern. The Company’s ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate additional revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Based on current plans the Company will be required to raise additional capital 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

## Table of Contents

•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 \$49.5 million of cash, cash equivalents and short-term investments at July 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 consolidated statement of operations under the caption "Change in fair value of derivative instruments."

The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding the volatility of Trovogene'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 June 30, 2016, and December 31, 2015, the fair value of these warrants was \$2,710,451 and \$3,297,077, respectively, and were included in the derivative financial instruments liability on the balance sheet.

Table of Contents

## Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, Earnings per Share, for all periods presented. In accordance with this guidance, basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Preferred dividends are included in income 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Numerator: Net loss attributable to common shareholders	\$(10,208,338)	\$(10,186,094)	\$(20,476,916)	\$(17,366,535)
Adjustment for change in fair value of derivative instruments - warrants	—	—	(533,750)	—
Net loss used for diluted loss per share	\$(10,208,338)	\$(10,186,094)	\$(21,010,666)	\$(17,366,535)
Denominator for basic and diluted net loss per share:				
Weighted average shares used to compute basic loss per share	29,958,037	24,592,883	29,856,611	23,212,963
Adjustments to reflect assumed exercise of warrants	—	—	176,596	—
Weighted average shares used to compute diluted net loss per share	29,958,037	24,592,883	30,033,207	23,212,963
Net loss per share attributable to common stockholders:				
Basic	\$(0.34	) \$(0.41	) \$(0.69	) \$(0.75
Diluted	\$(0.34	) \$(0.41	) \$(0.70	) \$(0.75

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:

	June 30,	
	2016	2015
Options to purchase Common Stock	6,137,495	5,898,597
Warrants to purchase Common Stock	4,515,947	5,703,242
Restricted Stock Units	396,500	—
Series A Convertible Preferred Stock	63,125	63,125
	11,113,067	11,664,964

## Recent Accounting Pronouncements

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

Table of Contents

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 June 30, 2016 and December 31, 2015:

	Fair Value Measurements at June 30, 2016			Total
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets:				
Money market fund (1)	\$22,152,272	\$—	\$ —	\$22,152,272
Corporate debt securities (2)	—	16,038,713	—	16,038,713
Commercial paper (2)	—	11,965,848	—	11,965,848
Total Assets	\$22,152,272	\$28,004,561	\$ —	\$50,156,833
Liabilities:				
Derivative liabilities related to warrants	\$—	\$—	\$ 2,710,451	\$2,710,451
Total Liabilities	\$—	\$—	\$ 2,710,451	\$2,710,451
	Fair Value Measurements at December 31, 2015			Total
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	



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

(Level 1)

Assets:

Money market fund (1)	\$65,016,222	\$	—\$ —	\$65,016,222
Total Assets	\$65,016,222	\$	—\$ —	\$65,016,222

Liabilities:

Derivative liabilities related to 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.

Table of Contents

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the six months ended June 30, 2016:

Description	Balance at December 31, 2015	Unrealized Gain	Balance at June 30, 2016
Derivative liabilities related to Warrants	\$3,297,077	\$(586,626)	\$2,710,451

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

#### 4. Investments

Investments consist of corporate debt securities and commercial paper. The Company classifies debt securities as available-for-sale and as current assets, 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 six months ended June 30, 2016.

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

	Maturity in Years	Cost	Unrealized		Fair Value
			Gains	Losses	
Corporate debt securities	Less than 1 year	\$16,033,581	\$9,106	\$(3,974)	\$16,038,713
Commercial paper	Less than 1 year	11,965,848	—	—	11,965,848
Total Investment		\$27,999,429	\$9,106	\$(3,974)	\$28,004,561

#### 5. Property and Equipment

Property and equipment consist of the following:

	As of June 30, 2016	As of December 31, 2015
Furniture and office equipment	\$1,658,105	\$1,483,227
Leasehold Improvements	1,964,310	39,401

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

Laboratory equipment	2,446,200	2,022,733
	6,068,615	3,545,361
Less—accumulated depreciation and amortization	(1,336,877 )	(854,782 )
Property and equipment, net	\$4,731,738	\$2,690,579

Table of Contents

## 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 June 30, 2016, the Company was in compliance with all covenants.

As of June 30, 2016, \$1,878,312 has been borrowed under the Equipment Line of Credit. As of June 30, 2016, amounts due under the Equipment Line of Credit included \$365,227 in current liabilities and \$1,528,527 in long-term liabilities, which includes \$15,442 of accrued final payment. The Company recorded \$48,846 in interest expense related to the Equipment Line of Credit during the six months ended June 30, 2016.

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

2016	\$365,227
2017	626,104
2018	626,104
2019	260,877
Total principal	1,878,312
Plus final fee premium accretion	15,442
Total long-term obligations	\$1,893,754

## Loan and Security Agreement

In June 2014, the Company entered into a \$15,000,000 loan and security agreement (“Agreement”) under which the lenders provided the Company a term loan, which was funded at closing. The interest rate is 7.07% per annum. Under the Agreement, the Company makes interest only payments on the outstanding amount of the loan on a monthly basis through February 2016, after which equal monthly payments of principal and interest are due until the loan maturity date of July 1, 2018. The loan is secured by a security interest in all of the Company’s assets except intellectual property, which is subject to a negative pledge. In connection with the loan, the lenders received a warrant to purchase an aggregate 85,470 shares of the Company’s common stock at an exercise price of \$3.51 per share exercisable for ten years from the date of issuance. The original value of the warrants, totaling \$235,857, was recorded as debt discount and additional paid-in capital as the warrants were equity classified. As of June 30, 2016, a warrant to purchase 42,735 shares of common stock remains outstanding.

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

The Company is also subject to certain affirmative and negative covenants under the Agreement, including limitations on its ability to: undergo certain change of control events; convey, sell, lease, license, transfer or otherwise dispose of any equipment financed by loans under the loan agreement; create, incur, assume, guarantee or be liable with respect to indebtedness, subject to certain exceptions; grant liens on any equipment financed under the loan agreement; and make or permit any payment on specified subordinated debt. In addition, under the Agreement, subject to certain exceptions, the Company is required to maintain with the lender its primary operating, other deposit and securities accounts. Furthermore, under the amendment to the Agreement, the Company is required to be in compliance with healthcare laws and regulations and terms and conditions of healthcare permits. The Company was in compliance with all covenants as of June 30, 2016.

Table of Contents

As of June 30, 2016, amounts due under the Agreement include \$5,781,517 in current liabilities, which include \$72,776 of current portion of debt discount, and \$7,502,862 in long-term liabilities, which include \$703,715 of accrued final payment. The Company recorded \$658,095 in interest expense related to the Agreement during the six months ended June 30, 2016.

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

2016	\$5,854,293
2017	6,281,871
2018	543,753
Total principal	12,679,917
Less discount	(99,253 )
Plus final fee premium accretion	703,715
Total long-term obligations	\$13,284,379

## 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, Trovogene determined that certain warrants issued in connection with the execution of certain equity financings must be recorded as derivative liabilities. In accordance with ASC Topic 815-40, the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant change in fair value is being recorded in the Company's statement of operations. The Company estimates the fair value of these warrants using the Black-Scholes option pricing model.

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

	Six Months Ended June 30,	
	2016	2015
Estimated fair value of Trovogene common stock	4.53-4.65	6.81-10.15
Expected warrant term	2.5-2.8 years	3.5-3.8 years
Risk-free interest rate	0.71-0.87%	0.89-1.01%
Expected volatility	82-89%	75-77%
Dividend yield	0	% 0 %

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

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

Date	Description	Warrants	Derivative Instrument Liability
	Balance of derivative financial instruments liability	967,295	\$3,297,077

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

December 31,  
2015

Change in fair value of warrants during the period recognized as a loss in the  
condensed consolidated statement of operations — (586,626 )

June 30, 2016 Balance of derivative financial instruments liability 967,295 \$2,710,451

13

---

Table of Contents

## 8. Stockholders' Equity

## Common Stock

During the six months ended June 30, 2016, the Company issued a total of 409,704 shares of Common Stock. 68,371 shares were issued upon exercise of options for a weighted average price of \$3.40, 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 Trovogene options have been recognized in operating results as follow:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Included in research and development expense	\$590,536	\$409,304	\$989,277	\$712,321
Included in cost of revenue	38,228	4,641	56,525	14,950
Included in selling and marketing expense	438,158	171,049	1,016,879	254,114
Included in general and administrative expense	234,991	538,452	2,050,340	853,802
Total stock-based compensation expense	\$1,301,913	\$1,123,446	\$4,113,021	\$1,835,187

The unrecognized compensation cost related to non-vested stock options outstanding at June 30, 2016 and 2015, net of expected forfeitures, was \$11,419,948 and \$8,918,735, 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 June 30, 2016 was approximately eight years.

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

	Six Months Ended June 30,			
	2016	2015		
Risk-free interest rate	1.5	% 1.82	%	
Dividend yield	0	% 0	%	
Expected volatility	102	% 76	%	
Expected term	5.5 years	6.2 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	3,032,050	5.02	
Exercised	(1,305,246 )	3.79	
Canceled / Forfeited	(2,431,162 )	5.40	
Expired	(106,777 )	11.14	
Balance outstanding, June 30, 2016	6,137,495	5.51	1,843,767
Exercisable at June 30, 2016	2,060,650	5.02	1,278,649



During the six months ended June 30, 2016, the Company had issued 996,000 options to its executive officers and non-employee directors that are over the authorized number of options in the Plan and are 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 statement of operations. Stockholder approval was obtained on May 17, 2016 to increase the

Table of Contents

number of authorized shares in the 2014 EIP Plan 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.

The Trovogene Inc. 2014 Equity Incentive Plan (the “2014 EIP”) originally had 2,500,000 shares of common stock authorized for issuance under the Plan. An additional 2,500,000 shares of common stock was authorized by the Board of Directors in March 2015 and approved by the Shareholders at the June 10, 2015 Annual Shareholders’ Meeting. An amendment to the 2014 EIP to increase the number of shares issuable to 7,500,000 shares from 5,000,000 shares was approved at the May 17, 2016 Annual Shareholders’ Meeting. As of June 30, 2016 there were 2,356,194 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 six months ended June 30, 2016. There were no restricted stock units granted during the year ended December 31, 2015.

A summary of our 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	(5,500 )	3.99
Non-vested restricted stock units outstanding, June 30, 2016	396,500	4.06

None of the restricted stock units vested during the six months ended June 30, 2016. At June 30, 2016, total unrecognized compensation cost related to non-vested restricted stock units was \$1,120,977, which is expected to be recognized over a weighted-average period of 6 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
Exercised	(50,000 )	8.00	
Balance outstanding, June 30, 2016	5,483,242	3.82	2.06

**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.

15

---

## Table of Contents

### Lease Agreement

The Company currently leases approximately 22,600 square feet of office and laboratory space at a monthly rental rate of approximately \$60,000. The lease will expire on December 31, 2021. On April 4, 2016, the Company entered into an amendment to the lease agreement which will expand the square footage of its office space to approximately 26,100 square feet at a monthly rental rate of approximately \$68,000. The new lease will expire on December 31, 2021. The new monthly rental rate will not be effective until the Company commences business operations in the expanded premises. The Company also leases certain office building in Torino, Italy, consisting 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 \$0.7 million for the six months ended June 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.

### 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 Trovogene securities. This form was declared effective on June 13, 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. Since the issuance of the Form S-3 on May 27, 2016, no amounts have been raised relating to this agreement.

### Database Usage

In March 2016 the Company entered into an agreement with an outside vendor to develop a database for test requisition and test results. Under the agreement, the Company is obligated to pay a fee each time an external user completes and submits a test order form to the database. As of June 30, 2016, the development had not yet been completed, and therefore, no payments are due.

### 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 Trovogene, 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 June 30, 2016, the Company has incurred approximately \$180,000 of legal expenses for services performed by Rutan & Tucker, LLP.

## Table of Contents

In September 2015, the Company entered into a research agreement with University of Turin (“University”) to collaborate on a program of research to develop, optimize and test molecular profiling tools for plasma and urine ctDNA in cancer. Dr. Alberto Bardelli, the Principal Investigator of the University who oversees this research program is also a member of the Scientific Advisory Board of the Company. Under the agreement, the Company has committed to pay up to \$529,000 for the services performed by the University. In addition, the Company may pay royalties to the University on revenue generated by the Company from the commercialization of any tools developed during the collaboration. As of June 30, 2016, the Company has incurred and recorded approximately \$258,000 of research and development expenses related to the agreement. No royalty expense has been incurred as of June 30, 2016.

### 11. Subsequent Event

#### Amendment to the Loan and Security Agreement

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, 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 March 1, 2017, after which equal monthly payments of principal and interest are due until the loan maturity date of February 1, 2020. The Company may be able to extend the interest only payments through September 1, 2017 based on agreed-upon milestones. The Company is also obligated to make a final payment equal to 7.50% of total funded amounts at the loan maturity date. In addition, each of the lenders received a warrant to purchase an aggregate 15,496 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.

## 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. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should not rely upon forward looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward looking statements will be achieved or occur. Although we believe

that the expectations reflected in the forward looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

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

## Table of Contents

### Overview

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

We are leveraging our proprietary molecular diagnostic technology for the detection of cell-free DNA originating from diseased cell death and that can be isolated and detected from urine, blood, and tissue samples to improve disease management.

These genetic materials are also collectively referred to as "cell-free nucleic acids", which result when cells in the body die and release their DNA contents into the bloodstream. The circulating fragments of genetic material are eventually filtered through the kidneys and therefore, can be detected and measured in urine. Cell-free nucleic acids can be used as genetic markers of disease. As such, the contents of urine or blood samples represent systemic liquid biopsies that can allow for simple, 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.

Our fundamental ctDNA diagnostic platform, also known as our Precision Cancer Monitoring<sup>SM</sup>, ("PCM") platform is protected by a strong intellectual property portfolio. We have developed significant intellectual property around cell-free nucleic acids in urine, the extraction of cell-free nucleic acids from urine, as well as novel assay designs, particularly our proprietary non-naturally occurring primers. Through this proprietary technology, we believe that we are at the forefront of a shift in the way diagnostic medicine is practiced, using simple, 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 June 30, 2016, our intellectual property portfolio consists of 90 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, and prenatal genetics.

We believe that our proprietary PCM platform is uniquely positioned to address a high unmet clinical need in field of oncology. Our PCM platform is designed to offer improved cancer monitoring by tracking and analyzing levels of cell-free DNA from either urine or blood samples, and is intended to provide important clinical information beyond the current standard of care. Using urine as a sample, our cancer monitoring technology enables more frequent, noninvasive monitoring of oncogene mutation status, disease progression and disease recurrence. Our research and development efforts were made commercially feasible following improved next-generation sequencing ("NGS") technologies which are now available at a significantly lower cost. This combined with our extensive patent portfolio around cell-free DNA in urine gives us a competitive advantage to leverage an emerging trend toward monitoring cancer using ctDNA as a marker of disease status. Our proprietary sample preparation process forms the basis of our PCM platform. It includes 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. We believe that our quantitative ctDNA detection and monitoring platform offers industry leading sensitivity, featuring single nucleic acid molecule detection.

Our PCM platform is poised to overcome a significant clinical dilemma in the area of cancer treatment. Recent scientific evidence supports the molecular basis of cancer, and has resulted in a paradigm shift in the way cancer is



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

## Table of Contents

While an improvement over chemotherapy in many cases, targeted drug therapies are not without issues, such as their high cost and potential side effects. In order to measure effectiveness of these therapies, repeated monitoring is needed and imaging and serial biopsies have their challenges or may not be optimal. If resistance develops to a targeted cancer therapy, fast and accurate detection of emerging or changing oncogene mutation status has potential to provide critical information early. Our PCM platform provides a novel solution for early detection of cancer progression using urine, a 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 June 30, 2016 is \$129,364,159. 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 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 160 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.

Clinical study results for our Trovera™ were presented by Heather Wakelee, M.D. of Stanford University at the ASCO. Results demonstrated highly sensitive detection of EGFR T790M mutations in the urine of patients with non-small cell lung cancer and validated urine ctDNA testing as an alternative to tissue and plasma based on a large prospective study of T790M detection and patient response to an EGFR tyrosine kinase inhibitor.

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

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

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

## Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of June 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.

Table of Contents

## RESULTS OF OPERATIONS

Three Months Ended June 30, 2016 and 2015

## Revenues

Our total revenues were \$103,400 and \$49,346 for the three months ended June 30, 2016 and 2015, respectively. The components of our revenues were as follows:

	Three Months Ended June 30,		
	2016	2015	Increase
Royalties	\$47,765	\$46,826	\$ 939
Diagnostic services	23,962	2,520	21,442
Clinical research services	\$31,673	\$—	31,673
Total revenues	\$103,400	\$49,346	\$54,054

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 clinical research and business development partners. Revenue was recognized when supplies were delivered. There was no such revenue for the three months ended June 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 \$409,463 for the three months ended June 30, 2016, compared to \$80,030 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 June 30, 2016 compared to the same period of last year 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:

	Three Months Ended June 30,		
	2016	2015	Increase
Salaries and staff costs	\$1,553,806	\$852,178	\$701,628
Stock-based compensation	590,536	409,304	181,232
Outside services, consultants and lab supplies	1,440,217	1,136,879	303,338
Facilities	408,554	209,981	198,573

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

Travel and scientific conferences	63,463	59,993	3,470
Other	19,838	15,822	4,016
Total research and development	\$4,076,414	\$2,684,157	\$1,392,257

Research and development expenses increased by \$1,392,257 to \$4,076,414 for the three months ended June 30, 2016 from \$2,684,157 for the same period in 2015. Our costs have increased mainly as a result of increased average number of our internal research and development personnel from twenty to thirty-five and increased consulting and outside services. We

Table of Contents

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 June 30, 2016 as compared to the same period in 2015. We expect research and development expenses to increase as we expand current clinical studies or enter into additional collaborations and further product development.

## Selling and Marketing Expenses

Selling and marketing expenses consisted of the following:

	Three Months Ended June 30,		
	2016	2015	Increase
Salaries and staff costs	\$1,430,199	\$777,238	\$652,961
Stock-based compensation	438,158	171,049	267,109
Outside services and consultants	318,711	285,250	33,461
Facilities	131,505	80,507	50,998
Trade shows, conferences and marketing	497,018	443,801	53,217
Travel	284,191	139,381	144,810
Other	29,254	18,624	10,630
Total sales and marketing	\$3,129,036	\$1,915,850	\$1,213,186

Selling and marketing expenses increased by \$1,213,186 to \$3,129,036 for the three months ended June 30, 2016 from \$1,915,850 for the same period in 2015. During the three months ended June 30, 2016 we increased the number of our field sales, customer support and marketing personnel, bringing our average headcount to twenty-two from thirteen 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 and printing services. We expect our selling and marketing expenses to further increase as we hire additional commercial team members that are focused on increasing market acceptance of our commercially available tests.

## General and Administrative Expenses

General and administrative expenses consisted of the following:

	Three Months Ended June 30,		
	2016	2015	Increase/(Decrease)
Personnel and outside services costs	\$1,114,943	\$866,163	\$ 248,780
Board of Directors' fees	121,058	115,204	5,854
Stock-based compensation	234,991	538,452	(303,461)
Legal and accounting fees	612,727	262,226	350,501
Facilities and insurance	265,539	99,154	166,385
Travel	27,441	24,183	3,258
Fees, licenses, taxes and other	92,033	96,134	(4,101)
Total general and administrative	\$2,468,732	\$2,001,516	\$ 467,216

General and administrative expenses increased by \$467,216 to \$2,468,732 for the three months ended June 30, 2016, from \$2,001,516 for the same period in 2015. The significant components of the increase were primarily due to the increase of personnel and outside services costs and legal and accounting fees, partially offset by a decrease in

stock-based compensation. 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

Table of Contents

general and administrative costs to increase to as our commercial operations and research and development teams grow and if we need to retain additional legal resources.

## Net interest Expense

Net interest expense was \$274,909 and \$381,252 for three months ended June 30, 2016 and 2015, respectively. The decrease of net interest expense is primarily due to an increase in interest income of approximately \$81,000, 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 three months ended June 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 Instruments - Warrants

We have issued securities that are accounted for as derivative liabilities. As of June 30, 2016, the derivative liabilities related to securities issued were revalued to \$2,710,451, resulting in an decrease in value of \$52,876 from March 31, 2016, based primarily upon the decrease in our stock price from \$4.65 at March 31, 2016 to \$4.53 at June 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 liabilities in the condensed consolidated statement of operations.

## Net Loss

Net loss and per share amounts were as follows:

	Three Months Ended June 30,		
	2016	2015	Increase (Decrease)
Net loss attributable to common shareholders	\$(10,208,338)	\$(10,186,094)	\$ 22,244
Net loss per common share — basic	\$(0.34)	\$(0.41)	\$ (0.07)
Net loss per common share — diluted	\$(0.34)	\$(0.41)	\$ (0.07)
Weighted average shares outstanding — basic	29,958,037	24,592,883	5,365,154
Weighted average shares outstanding — diluted	29,958,037	24,592,883	5,365,154

The \$22,244 increase in net loss attributable to common shareholders was primarily the result of a slight increase in revenues, decrease in interest expense, the gain from the change in fair value in derivative liabilities, offset by an increase in operating expenses, compared to the same period in the prior year. \$0.07 decrease in basic net loss per share was impacted by the increase in basic weighted average shares outstanding resulting from the sale and issuance of approximately 4.6 million shares of common stock through underwritten public offering, as well as the issuance of approximately 675,000 shares of common stock from the exercise of stock options and warrants.

## Six Months Ended June 30, 2016 and 2015

## Revenues

Our total revenues were \$223,886 and \$176,316 for the six months ended June 30, 2016 and 2015, respectively. The components of our revenues were as follows:

## Six Months Ended June 30,



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

	2016	2015	Increase (Decrease)
Royalties	\$160,633	\$171,630	\$ (10,997 )
Diagnostic services	31,580	4,686	26,894
Clinical research services	31,673	—	31,673
Total revenues	\$223,886	\$176,316	\$ 47,570

Table of Contents

The \$10,997 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 six months ended June 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. Revenue was recognized when supplies were delivered. There was no such revenue for the six months ended June 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 \$718,734 for the six months ended June 30, 2016, compared to \$256,455 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 six months ended June 30, 2016 compared to the same period of last year 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:

	Six Months Ended June 30,		
	2016	2015	Increase
Salaries and staff costs	\$2,856,066	\$1,642,120	\$1,213,946
Stock-based compensation	989,277	712,321	276,956
Outside services, consultants and lab supplies	2,621,596	2,054,076	567,520
Facilities	669,791	358,333	311,458
Travel and scientific conferences	106,242	96,082	10,160
Other	41,506	18,884	22,622
Total research and development	\$7,284,478	\$4,881,816	\$2,402,662

Research and development expenses increased by \$2,402,662 to \$7,284,478 for the six months ended June 30, 2016 from \$4,881,816 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 seventeen to thirty-two. 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 kit. 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 six months ended June 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.



Table of Contents

## Selling and Marketing Expenses

Selling and marketing expenses consisted of the following:

	Six Months Ended June 30,		
	2016	2015	Increase
Salaries and staff costs	\$2,838,775	\$1,077,368	\$1,761,407
Stock-based compensation	1,016,879	254,114	762,765
Outside services and consultants	675,669	435,930	239,739
Facilities	249,766	139,488	110,278
Trade shows, conferences and marketing	839,191	573,736	265,455
Travel	504,098	173,236	330,862
Other	62,210	56,631	5,579
Total sales and marketing	\$6,186,588	\$2,710,503	\$3,476,085

Selling and marketing expenses increased by \$3,476,085 to \$6,186,588 for the six months ended June 30, 2016 from \$2,710,503 for the same period in 2015. During the six months ended June 30, 2016 we increased the number of our field sales, customer support and marketing personnel, bringing our average headcount to twenty-two from ten 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:

	Six Months Ended June 30,		
	2016	2015	Increase/(Decrease)
Personnel and outside services costs	\$2,143,594	\$1,702,386	\$ 441,208
Board of Directors' fees	223,053	231,211	(8,158)
Stock-based compensation	2,050,340	853,802	1,196,538
Legal and accounting fees	1,382,524	568,789	813,735
Facilities and insurance	401,461	213,395	188,066
Travel	103,586	109,635	(6,049)
Fees, licenses, taxes and other	168,421	128,283	40,138
Total general and administrative	\$6,472,979	\$3,807,501	\$ 2,665,478

General and administrative expenses increased by \$2,665,478 to \$6,472,979 for the six months ended June 30, 2016, from \$3,807,501 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 and accounting fees. The increase of personnel and outside services costs is due to an increase in average headcount from five 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 six months ended June 30, 2016. Legal fees increased primarily as a result of lawsuit against the Company's former CEO and CFO, and review of federal and state tax regulations with respect to certain executive compensation. We expect our general and administrative costs to increase to as our commercial operations and research and development teams grow and if we

need to retain additional legal resources.

Table of Contents

## Net interest Expense

Net interest expense was \$612,529 and \$764,721 for six months ended June 30, 2016 and 2015, respectively. The decrease of net interest expense is primarily due to an increase in interest income of approximately \$131,000, 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 six months ended June 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 Instruments - Warrants

We have issued securities that are accounted for as derivative liabilities. As of June 30, 2016, the derivative liabilities related to securities issued were revalued to \$2,710,451, resulting in an decrease in value of \$586,626 from December 31, 2015, based primarily upon the decrease in our stock price from \$5.40 at December 31, 2015 to \$4.53 at June 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 liabilities in the condensed consolidated statement of operations.

## Net Loss

Net loss and per share amounts were as follows:

	Six Months Ended June 30,		
	2016	2015	Increase (Decrease)
Net loss attributable to common shareholders	\$(20,476,916)	\$(17,366,535)	\$ 3,110,381
Net loss per common share — basic	\$(0.69 )	\$(0.75 )	\$ (0.06 )
Net loss per common share — diluted	\$(0.70 )	\$(0.75 )	\$ (0.05 )
Weighted average shares outstanding — basic	29,856,611	23,212,963	6,643,648
Weighted average shares outstanding — diluted	30,033,207	23,212,963	6,820,244

The \$3,110,381 increase in net loss attributable to common shareholders reflected a slight increase in revenues, decrease in interest expense, and the gain from the change in fair value in derivative liabilities, offset by an increase in operating expenses, compared to the same period in the prior year. \$0.06 decrease in basic net loss per share was impacted by the increase in basic weighted average shares outstanding resulting from the sale and issuance of approximately 4.6 million shares of common stock through underwritten public offering, as well as the issuance of approximately 675,000 shares of common stock from the exercise of stock options and warrants.

## LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2016, we had \$22,578,980 in cash and cash equivalents. Net cash used in operating activities for the six months ended June 30, 2016 was \$14,993,428, compared to \$10,177,419 for the six months ended June 30, 2015. Our use of cash was primarily a result of the net loss of \$20,464,796 for the six months ended June 30, 2016, adjusted for non-cash items related to stock-based compensation of \$4,113,021, amortization of debt costs of \$181,318, accretion of discount on debt of \$52,641, depreciation and amortization of \$489,708, amortization of premiums on short-term investments of \$27,481, deferred rent of \$66,689, interest income accrued on short-term investments of \$75,300, and the loss from the change in fair value of derivatives of \$586,626. The changes in our operating assets and liabilities consisted of higher accounts payable and accrued expenses, an increase in prepaid expenses and accounts receivable, and a decrease in 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 \$28,622,478 during the six months ended June 30, 2016, compared to \$687,965 for the same period in 2015. Investing activities consisted of net purchases for capital equipment that used \$670,867 in cash, purchase of short-term investments of \$27,951,611.

Net cash used in financing activities was \$1,295,688 during the six months ended June 30, 2016, compared to \$24,865,370 provided by financing activities in 2015. Financing activities during the six months ended June 30, 2016 related primarily to the net payment of long-term debt offset by borrowings under equipment line of credit. Financing activities during

## Table of Contents

the same period of the prior year consisted primarily of proceeds from the sale of our common stock in underwritten public offerings. We completed a refinancing of our debt in July 2016 that resulted in additional cash provided by financing activities in the third quarter of 2016.

As of June 30, 2016, and December 31, 2015, we had working capital of \$40,730,842 and \$60,179,971, respectively. As of July 31, 2016, our working capital was \$45.6 million.

On July 20, 2016, Trovogene, Inc. (the “Company”) entered into a Fifth Amendment (the “Amendment”) to the Loan and Security Agreement with Oxford Finance LLC (“Oxford”) and Silicon Valley Bank (“SVB” and together with Oxford, the “Lenders”). Pursuant to the Amendment, the Company is required to make interest only payments on the outstanding amount of the loan on a monthly basis through March 1, 2017 and provided that (i) the Company has successfully secured agreements with insurance providers/networks resulting in 168 million aggregate U.S. covered lives and (ii) the Company’s Trovera EGFR, KRAS and BRAF products have been placed on a list of diagnostic tests at a major U.S. cancer center satisfactory to the Lenders, through September 1, 2017. In addition, the maturity date of the loan was amended to February 1, 2020. Further, each of the Lenders received a warrant to purchase an aggregate 15,496 shares of Company common stock at an exercise price of \$4.84 per share exercisable for ten years from the date of issuance.

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.

## Table of Contents

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 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 six months ended June 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 June 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 June 30, 2016 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

Except for the following risk factors, there have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2015.

We depend upon our officers and other key employees, and if we are not able to retain them or recruit additional qualified personnel, the commercialization of our product candidates and any future tests that we develop could be delayed or negatively impacted.

Our success is largely dependent upon the continued contributions of our officers, especially William Welch, our Chief Executive Officer, and other key employees. Our success also depends in part on our ability to retain our current employee base and continue to attract highly qualified scientific, commercial and administrative personnel. The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field and, in order to pursue our test development and commercialization strategies, we will need to attract, hire and retain, or engage as consultants, additional personnel with specialized experience in a number of disciplines, including assay development, bioinformatics and statistics, laboratory and clinical operations, clinical affairs and studies, government regulation, sales and marketing, billing and reimbursement and information systems. Additionally, there is intense competition for personnel in the fields in which we operate. If we are unable to attract new employees and retain existing employees, the development and commercialization of our product candidates and any tests we may develop in the future could be delayed or negatively impacted.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of June 30, 2016, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially owned approximately 26.9% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Table of Contents

ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit
4.1	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on July 26, 2016).
10.1	Fifth Amendment to Loan and Security Agreement dated as of July 20, 2016 by and among Oxford Finance LLC, Silicon Valley Bank, Trovogene, Inc. (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on July 26, 2016).
10.2	Form of Seventh Amendment to Standard Industrial Net Lease dated April 4, 2016 between Trovogene, Inc. and BMR-Coast 9 LP.
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 June 30, 2016 filed on August 4, 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.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TROVAGENE, INC.

August 4, 2016 By: /s/ William Welch

William Welch

Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)