

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

Trovogene, Inc.
Form 10-Q
May 08, 2018
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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 March 31, 2018

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

(State or other jurisdiction of incorporation or organization)

27-2004382

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

11055 Flintkote Avenue, Suite B, San Diego, California

(Address of principal executive offices)

92121

(Zip Code)

(858) 952-7570

(Registrant's telephone number, including area code)

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, smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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

Smaller reporting company

Emerging growth company

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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 April 30, 2018, the issuer had 59,378,162 shares of Common Stock issued and outstanding.

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TROVAGENE, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TROVAGENE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$6,657,158	\$8,225,764
Accounts receivable and unbilled receivable	114,343	77,095
Prepaid expenses and other current assets	1,068,144	1,165,828
Total current assets	7,839,645	9,468,687
Property and equipment, net	2,223,597	2,426,312
Other assets	345,277	389,942
Total Assets	\$10,408,519	\$12,284,941
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$651,671	\$825,244
Accrued expenses	1,685,178	1,454,587
Deferred rent	341,924	334,424
Current portion of long-term debt	1,174,989	1,331,515
Total current liabilities	3,853,762	3,945,770
Derivative financial instruments—warrants	779,076	649,387
Deferred rent, net of current portion	1,096,591	1,183,677
Total Liabilities	5,729,429	5,778,834
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, \$0.001 par value, 20,000,000 shares authorized; 60,600 shares outstanding at March 31, 2018 and December 31, 2017; designated as Series A Convertible Preferred Stock with liquidation preference of \$606,000 at March 31, 2018 and December 31, 2017	60	60
Common stock, \$0.0001 par value, 150,000,000 shares authorized; 58,832,953 and 52,791,584 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	5,883	5,279
Additional paid-in capital	182,401,648	179,546,954
Accumulated deficit	(177,728,501)	(173,046,186)
Total Stockholders' Equity	4,679,090	6,506,107
Total Liabilities and Stockholders' Equity	\$10,408,519	\$12,284,941

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended March	
	31,	
	2018	2017
Revenues:		
Royalties	\$49,055	\$65,826
Diagnostic services	40,002	28,862
Clinical research	11,079	350
Total revenues	100,136	95,038
Costs and expenses:		
Cost of revenues	366,344	616,426
Research and development	1,883,838	4,279,830
Selling, general and administrative	2,504,977	3,604,624
Restructuring charges	—	1,719,804
Total operating expenses	4,755,159	10,220,684
Loss from operations	(4,655,023)	(10,125,646)
Net interest expense	(2,465)	(429,397)
(Loss) gain from change in fair value of derivative financial instruments—warrants	(129,689)	555,506
Other income	1,000	—
Net loss	(4,786,177)	(9,999,537)
Preferred stock dividend	(6,060)	(6,060)
Net loss attributable to common stockholders	\$(4,792,237)	\$(10,005,597)
Net loss per common share — basic	\$(0.09)	\$(0.32)
Net loss per common share — diluted	\$(0.09)	\$(0.32)
Weighted-average shares outstanding — basic	55,364,438	30,961,014
Weighted-average shares outstanding — diluted	55,364,438	30,961,014

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2018	2017
Net loss	\$ (4,786,177)	\$ (9,999,537)
Other comprehensive loss:		
Foreign currency translation loss	—	(2,399)
Unrealized gain or reversal of previous losses on securities available-for-sale	—	(454)
Total other comprehensive loss	—	(2,853)
Total comprehensive loss	(4,786,177)	(10,002,390)
Preferred stock dividend	(6,060)	(6,060)
Comprehensive loss attributable to common stockholders	\$ (4,792,237)	\$ (10,008,450)

See accompanying notes to the unaudited condensed consolidated financial statements.

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TROVAGENE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited)

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, January 1, 2018	60,600	\$ 60	52,791,584	\$ 5,279	\$ 179,546,954	\$(173,046,186)	\$ 6,506,107
Stock-based compensation	—	—	—	—	1,406,131	—	1,406,131
Issuance of common stock upon exercise of warrants	—	—	5,136,667	514	1,448,653	—	1,449,167
Issuance of common stock upon vesting of restricted stock units	—	—	904,702	90	(90) —	—
Preferred stock dividend	—	—	—	—	—	(6,060) (6,060)
Cumulative adjustment upon adoption of ASC 606	—	—	—	—	—	109,922	109,922
Net loss	—	—	—	—	—	(4,786,177) (4,786,177)
Balance, March 31, 2018	60,600	\$ 60	58,832,953	\$ 5,883	\$ 182,401,648	\$(177,728,501)	\$ 4,679,090

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2018	2017
Operating activities		
Net loss	\$(4,786,177)	\$(9,999,537)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment loss	—	485,000
Depreciation and amortization	252,480	330,968
Stock based compensation expense	1,406,131	920,799
Accretion of final fee premium	—	125,012
Amortization of discount on debt	—	68,223
Amortization of premiums on short-term investments	—	10,877
Deferred rent	(79,586)	(66,119)
Interest income accrued on short-term investments	—	151,583
Change in fair value of derivative financial instruments—warrants	129,689	(555,506)
Changes in operating assets and liabilities:		
Decrease in accounts receivable and unbilled receivable	72,674	20,112
Decrease in prepaid expenses and other current assets	97,684	110,957
Increase (decrease) in accounts payable and accrued expenses	50,958	(360,577)
Net cash used in operating activities	(2,856,147)	(8,758,208)
Investing activities:		
Capital expenditures, net	(5,100)	(11,452)
Maturities of short-term investments	—	14,000,000
Purchases of short-term investments	—	(8,804,604)
Net cash (used in) provided by investing activities	(5,100)	5,183,944
Financing activities:		
Proceeds from exercise of warrants	1,449,167	—
Repayments of equipment line of credit	(156,526)	(156,526)
Net cash provided by (used in) financing activities	1,292,641	(156,526)
Effect of exchange rate changes on cash and cash equivalents	—	(844)
Net change in cash and equivalents	(1,568,606)	(3,731,634)
Cash and cash equivalents—Beginning of period	8,225,764	13,915,094
Cash and cash equivalents—End of period	\$6,657,158	\$10,183,460
Supplementary disclosure of cash flow activity:		
Cash paid for interest	\$16,417	\$300,040
Supplemental disclosure of non-cash investing and financing activities:		
Preferred stock dividends accrued	\$6,060	\$6,060

See accompanying notes to the unaudited condensed consolidated financial statements.

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

1. Organization and Basis of Presentation

Business Organization and Overview

Trovogene, Inc. (“Trovogene” or the “Company”) headquartered in San Diego, California, is a clinical-stage, oncology therapeutics company. The Company’s primary focus is to develop oncology therapeutics for the treatment of hematologic and solid tumor cancers for improved cancer care, utilizing its proprietary technology in tumor genomics.

Trovogene’s lead drug candidate, PCM-075, is a Polo-like Kinase 1 (“PLK1”) highly-selective adenosine triphosphate (“ATP”) competitive inhibitor. PCM-075 has shown preclinical antitumor activity as a single agent and synergy in combination with more than ten different chemotherapeutics, including cisplatin, cytarabine, doxorubicin, gemcitabine and paclitaxel, as well as targeted therapies, such as abiraterone acetate (Zytiga®), histone deacetylase (“HDAC”) inhibitors, such as belinostat (Beleodaq®), Quizartinib (AC220), a development stage FLT3 inhibitor, and bortezomib (Velcade®). These therapeutics are used clinically for the treatment of many hematologic and solid tumor cancers, including Acute Myeloid Leukemia (“AML”), Non-Hodgkin Lymphoma (“NHL”), metastatic Castration-Resistant Prostate Cancer (“mCRPC”), Adrenocortical Carcinoma (“ACC”), and Triple Negative Breast Cancer (“TNBC”).

PCM-075 was developed to have high selectivity to PLK1 (at low nanomolar IC₅₀ levels), to be administered orally, and to have a relatively short drug half-life of approximately 24 hours compared to other pan PLK inhibitors. A safety study of PCM-075 has been successfully completed in patients with advanced metastatic solid tumors and published in 2017 in Investigational New Drugs. The Company has two active Investigational New Drug (“INDs”) applications in place with the U.S. Food and Drug Administration (“FDA”) for PCM-075, allowing the Company to pursue clinical development in hematologic malignancies and solid tumor cancers. Trovogene is currently enrolling a Phase 1b/2 open-label clinical trial of PCM-075 in combination with standard-of-care chemotherapy in patients with AML. The Phase 1b/2 clinical trial is led by Hematologist Jorge Eduardo Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center. In addition, the Company is working with Dr. David Einstein at the Genitourinary Oncology Program at Beth Israel Deaconess Medical Center and Harvard Medical School as the principal investigator on a Phase 2 open-label clinical trial of PCM-075 in combination with abiraterone acetate (Zytiga®) and prednisone in patients with mCRPC with plans to enroll patients later this year.

Trovogene’s intellectual property and proprietary technology enables the Company to analyze circulating tumor DNA (“ctDNA”) and clinically actionable markers to identify patients most likely to respond to specific cancer therapies. The Company plans to continue to vertically integrate its tumor genomics technology with the development of targeted cancer therapeutics.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements of Trovogene, which include all accounts of its wholly owned subsidiary, Trovogene, Srl (dissolved in October 2017), 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 consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company's financial position and the results of its operations and cash flows for the periods presented. The unaudited condensed balance sheet at December 31, 2017 has been derived from the audited financial statements at that date but does not include all of the information and disclosures required by GAAP for annual financial statements. 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

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and the notes thereto for the year ended December 31, 2017 included in the Company's annual report on Form 10-K filed with the SEC on February 26, 2018.

Liquidity

Trovogene's condensed consolidated financial statements as of March 31, 2018 have been prepared under the assumption that Trovogene will continue as a going concern, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

The Company has incurred net losses since its inception and has negative operating cash flows. Considering the Company's current cash resources, management believes the Company's existing resources will be sufficient to fund the Company's planned operations through July 2018. On April 6, 2018, the Company paid off the outstanding Loan and Security Agreement ("Equipment Line of Credit") entered in November 2015 to Silicon Valley Bank ("SVB"). Based on its current business plan and assumptions, the Company expects to continue to incur significant losses and require significant additional capital to further advance its clinical trial programs and support its other operations. The Company has based its cash sufficiency estimates on its current business plan and its assumptions that may prove to be wrong. The Company could utilize its available capital resources sooner than it currently expects, and it could need additional funding to sustain its operations even sooner than currently anticipated. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional capital.

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.

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, all of which would have a material adverse impact on the Company's operations. The Company may also be required to:

- Seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and

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

The Company is evaluating all options to raise additional capital as well as reduce costs, in an effort to strengthen its liquidity position, which may include the following:

• Raising capital through public and private equity offerings;

• Introducing operation and business development initiatives to bring in new revenue streams;

• Reducing operating costs by identifying internal synergies; and

• Engaging in strategic partnerships.

As of April 30, 2018, the Company has received approximately \$1.6 million upon exercise of 5,681,667 warrants in connection with the December 2017 public offering. The Company continually assesses its spending plans to effectively and efficiently address its liquidity needs.

NASDAQ Notice

On September 5, 2017, the Company received a written notice from the NASDAQ Stock Market LLC (“NASDAQ”) that it was not in compliance with NASDAQ Listing Rule 5550(a)(2) for continued listing on the NASDAQ Capital Market, as the minimum bid price of the Company’s common stock had been below \$1.00 per share for 30 consecutive business days. In

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accordance with NASDAQ Listing Rule 5810(c)(3)(A), the Company has a period of 180 calendar days, or until March 5, 2018, to regain compliance with the minimum bid price requirement.

On March 6, 2018, the NASDAQ Capital Market informed the Company that it is eligible for an additional 180 calendar day period until September 4, 2018 to regain compliance with the minimum \$1.00 bid price per share requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed \$1.00 per share for at least ten consecutive business days during this 180 calendar day period.

2. Summary of Significant Accounting Policies

During the three months ended March 31, 2018, there have been no changes to the Company's significant accounting policies as described in its Annual Report on Form 10-K for the fiscal year ended December 31, 2017, except as described below.

Revenue Recognition

The Company recognizes revenue when control of its products and services is transferred to its customers in an amount that reflects the consideration it expects to receive from its customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control. For sales-based royalties, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

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 are earned based on the licensee's use. The Company estimates and records licensee's sales based on historical usage rate and collectability.

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. This revenue stream does not meet the criteria for contracts with a customer under ASC

606 because it is not probable that the Company will collect substantially all the consideration to which it will be entitled in exchange for the goods and services transferred, nor can it reliably determine the expected transaction price. Therefore, 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.

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Clinical Research Revenue

Revenue from clinical research consists of revenue from the sale of urine and blood collection supplies and tests performed under agreements with our clinical research and business development partners. Revenue is recognized when supplies and/or test results are delivered, which is when control of the product is deemed to be transferred.

Refer to Note 3 to the condensed consolidated financial statements for further information.

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 March 31,	
	2018	2017
Numerator: Net loss attributable to common shareholders	\$(4,792,237)	\$(10,005,597)
Adjustment for gain from change in fair value of derivative financial instruments—warrants	—	—
Net loss used for diluted loss per share	\$(4,792,237)	\$(10,005,597)
Denominator for basic and diluted net loss per share:		
Weighted-average shares used to compute basic loss per share	55,364,438	30,961,014
Adjustments to reflect assumed exercise of warrants	—	—
Weighted-average shares used to compute diluted net loss per share	55,364,438	30,961,014
Net loss per share attributable to common stockholders:		
Basic	\$(0.09)	\$(0.32)
Diluted	\$(0.09)	\$(0.32)

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:

	March 31,	
	2018	2017
Options to purchase Common Stock	7,588,306	4,687,566
Warrants to purchase Common Stock	18,418,853	5,505,901
Restricted Stock Units	369,600	976,991
Series A Convertible Preferred Stock	63,125	63,125
	26,439,884	11,233,583

Change in Accounting Principle

In August 2016, the FASB issued Accounting Standards Update (“ASU”) 2016-15, Classification of Certain Cash Receipts and Cash Payments (“ASU 2016-15”), which includes amendments that clarify how certain cash receipts and cash payments are presented in the statement of cash flows. ASU 2016-15 also provides guidance clarifying when an entity should separate cash receipts and cash payments and classify them into more than one class of cash flows. The Company adopted ASU 2016-15 as of January 1, 2018. The adoption of ASU 2016-15 had no material impact on its consolidated statements of cash flows.

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In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (“ASU 2014-09”). The new standard is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Since its initial release, the FASB has issued several amendments to the standard, which include clarification of accounting guidance related to identification of performance obligations, intellectual property licenses, and principle versus agent considerations. ASU 2014-09 and all subsequent amendments (collectively, “ASC 606”) became effective for the Company on January 1, 2018. The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. Refer to Note 3 to the condensed consolidated financial statements for further details.

Recent Accounting Pronouncements

In February 2016, the FASB issued 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 most leases. 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 new standard will impact the Company’s accounting for its office leases and the Company is currently evaluating the impact of the new standard on its consolidated financial statements.

3. Revenue

Financial Statement Impact of Adopting ASC 606

The Company adopted ASC 606 using the modified retrospective method. This resulted in a cumulative adjustment to decrease the Company’s accumulated deficit by \$109,922 to reflect the acceleration of revenue recognition related to its sales-based royalties for agreements with customers that were not completed as of January 1, 2018. As a result of applying the modified retrospective method to adopt the new revenue guidance, the Company recorded \$109,922 to unbilled receivables under the condensed consolidated balance sheet as of January 1, 2018.

Impact of New Revenue Guidance on Financial Statement Line Items

The following summarizes the significant changes to the Company’s condensed consolidated balance sheet and condensed consolidated statement of operations for the three months ended March 31, 2018 as a result of the adoption of ASC 606 on January 1, 2018 compared to what would have been recognized under ASC 605:

Total reported assets and equity were \$30,667 greater than what would have been reported under ASC 605 as of March 31, 2018. This was due to the acceleration of future minimum customer sales-based royalty revenues under ASC 606 through the potential contract cancellation period.

\$77,589 reduction of recorded revenues related to prior periods. Previously under ASC 605, there was a lag of at least one quarter before the Company was notified of customers’ sales-based royalties, and thus royalty revenues in excess of the minimum guaranteed amounts were recognized in arrears. This would have resulted in recording additional royalty revenue in the first quarter of 2018 related to eligible 2017 customer sales. For customers that only report royalty-eligible sales annually, this typically resulted in the recognition of a full year’s worth of royalties in excess of the minimum in the first quarter of the following year. However, ASC 606 requires recognition in the period earned even if amounts are unknown (subject to the constraint that a significant future reversal of this estimated revenue is not probable). Because the modified retrospective approach was applied upon adoption on January 1, 2018, this

cumulative difference (amount in arrears) was adjusted to the Company's accumulated deficit rather than recording this revenue in the first quarter of 2018.

Partially offsetting the reduction above is the \$18,326 acceleration of first quarter 2018 sales-based royalty revenue in excess of minimum guaranteed amounts to the extent the amounts are known or can be estimated, and a significant reversal is not probable.

The net impact of accounting for revenue under the new guidance increased net loss and net loss per share by \$59,263 and \$0.001 per basic and diluted share, respectively for the three months ended March 31, 2018.

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The adoption of ASC 606 had no impact on the Company's cash flows from operations. The aforementioned impacts resulted in offsetting shifts in cash flows between net loss and changes in working capital balances.

Revenue Recognitions

The Company has historically derived its revenues from the following sources: (i) royalties from sublicense and patent transfer agreements, (ii) up-front fees from sublicense and patent transfer agreements, (iii) milestone payments from sublicense and patent transfer agreements, (iv) diagnostic services revenue and (v) clinical research revenue. These revenue streams are discussed in greater detail below.

Royalty Revenue

Royalties have comprised the majority of the Company's revenues to date. Its licensing and patent transfer agreements provide for ongoing royalties, generally calculated as a percentage of net revenues related to the licensed or transferred intellectual property ("IP"). In addition, many of its agreements specify a minimum annual royalty amount beginning in the year of the customer's first related sale. Because minimum royalty amounts are contractually guaranteed, they are considered fixed consideration and allocated to the performance obligations at the stated amounts in the agreements. Sales-based royalties in excess of the minimum amount are considered variable consideration as the amounts are not known until the related customer sales occur, and are therefore excluded from the transaction price. Royalty amounts are reported by customers on a quarterly or annual basis, depending on the agreement, and are typically collected by the Company in the following quarter.

Under ASC 606, fixed consideration is recognized as revenue when all performance obligations have been satisfied. For existing licensing and patent transfer agreements, the sole performance obligation was the issuance of the sublicense or the transfer of the patent which occurred at the agreements' inception. However, as these agreements are generally cancellable by either party with 60-90 days' notice, a fixed contractual minimum cannot be determined at the outset of the agreement. Thus, at a given point the Company may only recognize minimum royalty revenue to be received 60-90 days in the future, as there are no guarantees beyond the minimum cancellation period. This is a slight acceleration compared to previous guidance, which did not permit future minimum royalties to be recognized in an earlier period. The cumulative adjustment to accumulated deficit upon adoption at January 1, 2018 related to this acceleration in revenue recognition was not material, at approximately \$32,000.

Sales-based royalties in excess of annual minimums are considered variable consideration. Sales-based or usage-based royalty based on an intellectual property license prohibits recognition of the royalty until sales or other activities occur. Historically, there has been a short lag before the Company was notified of a customer's previous period sales, and thus sales greater than minimum royalties were recognized in arrears as these amounts became known. Under ASC 606 the Company is now required to record an estimate of sales in excess of minimums even if the exact amount is unknown. Given the Company's relatively low revenues overall and the unpredictable nature of these sales-based royalties, such acceleration under ASC 606 has not been material. A cumulative adjustment of approximately \$78,000 was recognized upon adoption as a result of this acceleration. Amounts that have been recognized as revenue but not yet billed to customers are presented as unbilled receivables on the Company's balance sheet.

Up-Front Licensing and Patent Transfer Fees

Each of the Company's licensing agreements contains a non-refundable up-front licensing fee for use by the customer of the related IP. The Company's IP license grants and patent transfers are considered to be functional IP as each has immediate standalone value and distinct performance obligations and as such, revenue is recognized upon transfer of control to the customer. This is considered fixed consideration under ASC 606 and is allocated entirely to the IP grant

at the amount stated in the agreement. This is consistent with the previous guidance and as such, the adoption of ASC 606 had no effect on this revenue stream as all performance obligations under existing agreements had already been satisfied, fees had been collected from customers, and the related revenues had already been recognized prior to adoption.

Milestone Payments from Sublicense and Patent Transfer Agreements

A few of the Company's agreements with customers contain payments related to the achievement of specific milestones. However, as no milestones have been reached under these agreements in several years and the Company does not expect to achieve the remaining milestones under existing agreements, these potential amounts are excluded from the transaction price, and the adoption of ASC 606 had no effect on this revenue stream. The Company will, however, continue to update its assessment in future reporting periods regarding the likelihood of achieving outstanding milestones.

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Diagnostic Service Revenue

This revenue stream is related to the performance of clinical laboratory tests and has come primarily from insurance companies and government payors, such as Medicare and Medicaid in the United States. Some revenue also comes from international private payors. Diagnostic services revenue to date has been recognized on a cash collection basis due to (i) the highly complex insurance and governmental regulations and practices that vary based on state, third party payor, etc., (ii) the Company's relatively short commercial history with uncollected billings, (iii) the Company's fairly high percentage of services that are billed and not collected, and (iv) significant lag times between when a sample is processed and when payment is received. While distinct performance obligations and stand-alone selling prices can be identified, we do not believe these agreements meet the criteria for contracts with a customer under ASC 606 because it is not probable that the entity will collect substantially all the consideration to which it will be entitled in exchange for the goods and services transferred, nor can it reliably determine the expected transaction price. Therefore, the Company has continued to recognize this revenue on a cash basis as it did under the previous guidance. Thus, the adoption of ASC 606 did not affect this revenue stream.

Clinical Research Revenue

This revenue stream consists primarily of sales of urine and blood collection supplies and testing services under agreements with distributors and with pharmaceutical companies. These agreements meet the criteria for contracts with a customer, have fixed prices and quantities for goods (supplies) and services (tests), and each good or service represents a distinct performance obligation and has a stand-alone selling price that is independent of other purchases by the customer. Performance obligations are satisfied when goods or services are provided to the customer under ASC 606. Because testing services are very short in duration (less than two weeks) and have relatively low prices and low volumes, related costs are expensed immediately rather than recorded as contract assets, as the results would not differ significantly. Standard payment terms apply to these agreements, and thus there is no financing component nor prepayments that would result in a contract liability. Customers are invoiced and revenue is recognized simultaneously upon shipment or delivery of test results at the stated amounts per the contract, which is consistent with previous guidance. Thus, the adoption of ASC 606 did not affect reported amounts for this revenue stream.

Transaction Price Allocated to Future Performance Obligations

Licensing and patent transfer agreements may contain three possible revenue sources: up-front licensing fees, sales-based royalties and potential milestone revenue. However, all of the Company's existing agreements of this type contained only a single performance obligation to provide the functional IP to the customer at the outset of the agreement. While the Company continues to receive related sales-based royalties, the related performance obligations were satisfied in previous years and thus the Company has no future performance obligations under these agreements.

4. 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 March 31, 2018 and December 31, 2017:

Fair Value Measurements at March 31, 2018			
Quoted Prices in Active Markets for	Significant Other Observable	Significant Unobservable Inputs	Total

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	Identical Assets and Liabilities (Level 1)	Inputs (Level 2)	(Level 3)	
Assets:				
Money market fund (1)	\$6,840,505	\$	—\$ —	\$6,840,505
Total Assets	\$6,840,505	\$	—\$ —	\$6,840,505
Liabilities:				
Derivative financial instruments—warrants	\$—	\$	—\$ 779,076	\$779,076
Total Liabilities	\$—	\$	—\$ 779,076	\$779,076

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	Fair Value Measurements at December 31, 2017			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)	\$8,309,964	\$	—\$ —	\$8,309,964
Total Assets	\$8,309,964	\$	—\$ —	\$8,309,964
Liabilities:				
Derivative financial instruments—warrants	\$—	\$	—\$ 649,387	\$649,387
Total Liabilities	\$—	\$	—\$ 649,387	\$649,387

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

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the three months ended March 31, 2018:

Description	Balance at December 31, 2017	Realized (gains) or losses	Balance at March 31, 2018
Derivative financial instruments—warrants	\$ 649,387	\$ 129,689	\$ 779,076

The change in the fair value of the “derivative financial instruments—warrants” is recorded as a gain or loss in the Company's 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 and ASC Topic 480-10. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments that trade infrequently and therefore have little or no price transparency are classified as Level 3.

5. Property and Equipment

Property and equipment consist of the following:

	As of March 31, 2018	As of December 31, 2017
Furniture and office equipment	\$1,076,709	\$1,076,709
Leasehold improvements	1,994,514	1,994,514
Laboratory equipment	1,431,681	1,426,581
	4,502,904	4,497,804
Less—accumulated depreciation and amortization	(2,279,307)	(2,071,492)
Property and equipment, net	\$2,223,597	\$2,426,312

6. Equipment Line of Credit

In November 2015, the Company entered into a Loan and Security Agreement (“Equipment Line of Credit”) with SVB 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. At March 31, 2018, the interest rate was 6.00%. Interest only payments are due on borrowings through November 30, 2016, with both interest and principal payments commencing in December 2016. 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.

On June 20, 2017, the Company received a Notice of Event of Default (“Default Letter”) from SVB which stated that Events of Default had occurred and SVB will decide in its sole discretion whether or not to exercise rights and remedies. The Company does not agree that the loan is in Default, but pursuant to the Default Letter from SVB, the Company classified the

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entire balance of \$1,174,989 as a current liability as of March 31, 2018 and also recorded accrued interest at a default rate. The Company recorded \$24,236 in interest expense related to the Equipment Line of Credit during the three months ended March 31, 2018.

The Company paid off the Equipment Line of Credit on April 6, 2018. Refer to Note 10 to the condensed consolidated financial statements for further information.

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 ("ASC 815-40") or ASC Topic 480-10, Distinguishing Liabilities from Equity ("ASC 480-10"), 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 815-40 and ASC 480-10, the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant change in fair value is being recorded in the Company's condensed consolidated statements of operations. The Company estimates the fair value of these warrants using the Black-Scholes option pricing model.

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

	Three Months Ended March 31,		
	2018	2017	
Estimated fair value of Trovogene common stock	0.31-0.35	1.15-2.10	
Expected warrant term	0.8-5.1 years	1.8-2.0 years	
Risk-free interest rate	1.76-2.54%	1.20-1.27%	
Expected volatility	91-116%	94-98%	
Dividend yield	0	% 0	%

Expected volatility is based on historical volatility of Trovogene's common stock. The warrants have a transferability provision and based on guidance provided in Staff Accounting Bulletin ("SAB") No. 107, Share-Based Payment ("SAB No. 107"), for instruments issued with such a provision, Trovogene used the remaining contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates consistent with the expected remaining term of the warrants at each balance sheet date.

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

Date	Description	Number of Warrants	Derivative Instrument Liability
December 31, 2017	Balance of derivative financial instruments—warrants liability	5,610,921	\$ 649,387
	Change in fair value of derivative financial instruments—warrants during the period recognized as a loss in the condensed consolidated statements of operations	—	129,689
March 31, 2018	Balance of derivative financial instruments—warrants liability	5,610,921	\$ 779,076

8. Stockholders' Equity

Common Stock

During the three months ended March 31, 2018, the Company issued a total of 6,041,369 shares of Common Stock. 5,136,667 shares were issued upon exercise of warrants for a weighted-average price of \$0.28. In addition, 904,702 shares were issued upon vesting of restricted stock units (“RSU”).

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Stock Options

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

	Three Months Ended	
	March 31,	
	2018	2017
Included in research and development expense	\$395,709	\$372,200
Included in cost of revenue	39,631	26,156
Included in selling, general and administrative expense	970,791	601,309
Benefit from restructuring	—	(78,866)
Total stock-based compensation expense	\$1,406,131	\$920,799

The unrecognized compensation cost related to non-vested stock options outstanding at March 31, 2018 and 2017, net of expected forfeitures, was \$2,662,066 and \$5,677,247, respectively, which is expected to be recognized over a weighted-average remaining vesting period of 1.8 and 2.6 years, respectively. The weighted-average remaining contractual term of outstanding options as of March 31, 2018 was approximately 8.1 years. The total fair value of stock options vested during the three months ended March 31, 2018 and 2017 was \$971,488 and \$1,526,211, respectively.

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:

	Three Months Ended	
	March 31,	
	2018	2017
Risk-free interest rate	2.43	% 0 %
Dividend yield	0	% 0 %
Expected volatility	90.28	% 0 %
Expected term	5.2 years	0

(1) No options granted during the three months ended March 31, 2017.

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, 2017	4,490,475	\$ 4.04	\$—
Granted	3,132,831	\$ 0.30	
Canceled / Forfeited	(35,000)	\$ 5.82	
Balance outstanding, March 31, 2018	7,588,306	\$ 2.49	\$154,135
Exercisable at March 31, 2018	5,156,223	\$ 2.71	\$109,892

On June 13, 2017, the number of authorized shares in the Trovogene 2014 Equity Incentive Plan (“2014 EIP”) was increased from 7,500,000 to 9,500,000. As of March 31, 2018 there were 338,957 shares available for issuance under

the 2014 EIP.

Restricted Stock Units

There were no RSU granted during the three months ended March 31, 2018. The weighted-average grant date fair value of the RSU \$2.05 per share during the three months ended March 31, 2017.

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A summary of the RSU activity is presented below:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Intrinsic Value
Non-vested RSU outstanding, December 31, 2017	1,274,302	\$ 1.43	\$391,848
Vested	(904,702)	\$ 1.18	\$266,461
Non-vested RSU outstanding, March 31, 2018	369,600	\$ 2.05	\$129,064

At March 31, 2018 and 2017, total unrecognized compensation costs related to non-vested RSU were \$602,134 and \$1,603,214, which are expected to be recognized over a weighted-average period of 2.8 and 3.3 years, respectively. The total fair values of vested RSU during the three months ended March 31, 2018 and 2017 were \$1,070,914 and \$1,091,580, respectively.

Warrants

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

	Total Warrants (1)	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (1)
Balance outstanding, December 31, 2017	23,238,853	\$ 0.95	4.4
Exercised	(4,820,000)	\$ 0.30	
Balance outstanding, March 31, 2018	18,418,853	\$ 1.11	4.0

(1) Excluded the pre-funded warrants to purchase 316,667 shares of common stock at a nominal exercise price of \$0.01 per share. The pre-warrants were exercised in full during the three months ended March 31, 2018.

9. Commitments and Contingencies

Employment Agreements

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

Lease Agreements

The Company leases approximately 26,100 square feet of office and laboratory space at a monthly rental rate of approximately \$68,000. The lease will expire on December 31, 2021. The Company currently subleases certain office space and records the rental receipt under the subleases as a reduction of its rent expense.

License and Service Agreements

In March 2017, the Company entered into a license agreement with Nerviano Medical Sciences S.r.l. (“Nerviano”) which granted the Company development and commercialization rights to NMS-1286937, which Trovogene refers to as PCM-075. PCM-075 is an oral, investigative drug and a highly-selective adenosine triphosphate competitive inhibitor of the serine/threonine PLK 1. The Company plans to develop PCM-075 in patients with hematologic malignancies and solid tumor cancers. Upon execution of the agreement, the Company paid \$2.0 million in license

fees which were expensed to research and development costs during the year ended December 31, 2017. Under the agreement, the Company is committed to pay \$1.0 million for services provided by Nerviano, such as the costs to manufacture drug product, no later than June 30, 2019. As of March 31, 2018, approximately \$200,000 has been paid for services provided. Terms of the agreement also provide for the Company to pay royalties based on certain development and sales milestones.

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.

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Litigation

Trovogene does not believe that the Company has legal liabilities that are probable or reasonably possible that require either accrual or disclosure. From time to time, the Company may become involved in various lawsuits and legal proceedings that arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in matters may arise from time to time that may harm the Company's business. As of the date of this report, management believes that there are no claims against the Company, which it believes will result in a material adverse effect on the Company's business or financial condition.

10. Subsequent Event

On April 6, 2018, the Company paid approximately \$1,100,000 to SVB. This payment repaid the outstanding Equipment Line of Credit loan in full.

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, 2017, filed on February 26, 2018. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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

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

Overview

We are a clinical-stage, oncology therapeutics company. Our primary focus is to develop oncology therapeutics for the treatment of hematologic and solid tumor cancers for improved cancer care, utilizing our technology in tumor genomics.

On March 15, 2017, we announced that we licensed PCM-075, a PLK1 inhibitor, from Nerviano, pursuant to a license agreement with Nerviano dated March 13, 2017. PCM-075 was developed to have high selectivity to PLK1 (at low nanomolar IC_{50} levels), to be administered orally, and to have a relatively short drug half-life of approximately 24 hours compared to other pan PLK inhibitors. A safety study of PCM-075 has been successfully completed in patients with advanced metastatic solid tumors and published in 2017 in *Investigational New Drugs*. We currently are enrolling a Phase 1b/2 open-label clinical trial of PCM-075 in combination with standard-of-care chemotherapy in patients with AML. The Phase 1b/2 clinical trial is led by

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Hematologist Jorge Eduardo Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center. In addition, we are working with Dr. David Einstein at the Genitourinary Oncology Program at Beth Israel Deaconess Medical Center and Harvard Medical School as the principal investigator on a Phase 2 open-label clinical trial of PCM-075 in combination with abiraterone acetate (Zytiga®) and prednisone in patients with mCRPC with plans to enroll patients later this year.

Our intellectual property and proprietary technology enables us to analyze ctDNA and clinically actionable biomarkers to identify patients most likely to respond to specific cancer therapies. We plan to continue to vertically integrate our tumor genomics technology with the development of targeted cancer therapeutics.

We believe PCM-075 is the only PLK1 selective ATP competitive inhibitor, administered orally, with apparent antitumor activity in different preclinical models, currently in clinical trials. Polo-like kinase family consists of 5 members (PLK1-PLK5) and they are involved in multiple functions in cell division, including the regulation of centrosome maturation, checkpoint recovery, spindle assembly, cytokinesis, apoptosis and many others. PLK1 is essential for the maintenance of genomic stability during cell division (“mitosis”). The overexpression of PLK1 can lead to immature cell division followed by aneuploidy and cell death, a hallmark of cancer. PLK1 is over-expressed in a wide variety of hematologic and solid tumor malignancies, including acute myeloid leukemia, prostate, lung, breast, ovarian and adrenocortical carcinoma. In addition, several studies have shown that over-expression of PLK1 is associated with poor prognosis.

Studies have shown that inhibition of polo-like-kinases can lead to tumor cell death, including a Phase 2 study in AML where response rates with a different PLK inhibitor were up to 31% were observed when used in conjunction with a standard therapy for AML (low-dose cytarabine-LDAC) versus treatment with LDAC alone with a 13.3% response rate. We believe the more selective nature of PCM-075 to PLK1, its 24-hour half-life and oral bioavailability, as well as the reversibility of its on-target hematological toxicities may prove useful in addressing clinical therapeutic needs across a variety of cancers.

PCM-075 has been tested in vivo in different xenograft and transgenic models suggesting tumor growth inhibition or tumor regression when used in combination with other therapies. PCM-075 has been tested for antiproliferative activity on a panel of 148 tumor cell lines and appeared highly active with an IC₅₀ (a measure concentration for 50% target inhibition) below 100 nM in 75 cell lines and IC₅₀ values below 1 uM in 133 out of 148 cell lines. PCM-075 also appears active in cells expressing multi-drug resistant (“MDR”) transporter proteins and we believe PCM-075’s apparent ability to overcome the MDR transporter resistance mechanism in cancer cells could prove useful in broader drug combination applications.

In preclinical studies, synergy (interaction of discrete drugs such that the total effect is greater than the sum of the individual effects) has been demonstrated with PCM-075 when used in combination with more than ten different chemotherapeutics, including cisplatin, cytarabine, doxorubicin, gemcitabine and paclitaxel, as well as targeted therapies, such as abiraterone acetate (Zytiga®), HDAC inhibitors, such as belinostat (Beleodaq®), Quizartinib (AC220), a development stage FLT3 inhibitor, and bortezomib (Velcade®). These therapeutics are used clinically for the treatment of many hematologic and solid tumor cancers, including AML, NHL, mCRPC, ACC, and TNBC.

On August 16, 2017, we announced results of preclinical research indicating potential synergy of PCM-075 with an investigational FLT3 Inhibitor, Quizartinib by Daiichi Sankyo, in FLT3 mutant xenograft mouse models. This synergy assessment study was conducted for us by a third-party contract research group. Approximately one third of AML patients harbor FLT3-mutated blood cancer cells. The FDA recently approved Rydapt® (midostaurin) by Novartis for the treatment of newly diagnosed adult patients with AML that are FLT3 mutation-positive in combination with cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy. There are three FLT3 inhibitors in

ongoing phase 3 trials, including Quizartinib. We believe that a combination of PCM-075 with a FLT3 inhibitor for AML patients with a FLT3 mutation could extend treatment response and possibly slow or reduce resistance to FLT3 activity.

On August 21, 2017, we announced results of preclinical research indicating potential synergy of PCM-075 with a HDAC inhibitor in NHL cell lines. This synergy assessment study was conducted by Dr. Steven Grant, Associate Director for Translational Research and co-Leader, Developmental Therapeutics Program, Massey Cancer Center. Patients with relapsed or refractory NHL, such as cutaneous T cell lymphoma and peripheral T cell lymphoma, may be prescribed approved HDAC inhibitors and we believe this continues to be an area of unmet medical need. Dr. Grant's data appeared to indicate that the combination of PCM-075 with Beleodaq® (belinostat), an HDAC inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma, reduced cancer cells by up to 80% in two different forms of NHL (aggressive double-hit B-cell lymphoma and mantle cell lymphoma) cell lines.

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On October 11, 2017, we entered into a Patent Option Agreement with Massachusetts Institute of Technology (“MIT”) for the exclusive rights to negotiate a royalty-bearing, limited-term exclusivity license to practice world-wide patent rights to US Patent 9,566,280, subject to the rights of MIT (research, testing, and educational purposes), Ortho McNeil Pharmaceuticals-Janssen Pharmaceuticals and its Affiliates (internal research and pre-clinical drug development purposes including some laboratory research) and the federal government (government-funded inventions claimed in any patent rights and to exercise march in rights). This patent is generally directed to combination therapies including an antiandrogen or androgen antagonist and polo-like kinase inhibitor for the treatment of cancer. The Patent Option Agreement expires one-year from the effective date and includes other requirements to maintain the option period.

On October 18, 2017, we announced results of preclinical research indicating potential synergy of PCM-075 with abiraterone acetate in C4-2 prostate cancer cells. This synergy assessment study was conducted by Dr. Michael Yaffe, David H. Koch Professor of Biology and Biological Engineering at MIT. The results appeared to indicate that the combination of PCM-075 with Zytiga® (abiraterone acetate) decreased cell viability in mCRPC tumor cells and the apparent synergy observed was greater than the expected effect of combining the two drugs. Zytiga® is indicated for use in combination with prednisone for the treatment of patients with mCRPC who have received prior chemotherapy containing docetaxel. We believe there is an unmet medical need to improve on the resistance to hormone therapy and extend the benefit of response to abiraterone for mCRPC patients.

On December 7, 2017, we announced results of preclinical research showing the sensitivity of TNBC cell lines to PCM-075, data featured as a Poster Presentation at the 40th San Antonio Breast Cancer Symposium. This synergy assessment study was conducted by Dr. Jesse Patterson and Dr. Michael Yaffe, at MIT. The results appeared to indicate that TNBC cell lines are 20-fold more sensitive to PCM-075 than estrogen receptor positive (ER+) breast cancer cell lines.

Our accumulated deficit through March 31, 2018 is \$177,728,501. 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 2018, we have advanced our business with the following activities:

Announced initiation plans for a Phase 2 clinical trial evaluating the combination of PCM-075 and abiraterone acetate (Zytiga®- Johnson & Johnson) in patients with mCRPC. This study is designed to have 3 clinical sites, with Dr. David Einstein at the Genitourinary Oncology Program at Beth Israel Deaconess Medical Center and Harvard Medical School as the principal investigator.

Presented data showing synergy of PCM-075 in combination with Zytiga® in a Castration-Resistant Prostate Cancer Model at the 2018 Genitourinary Cancers Symposium (ASCO GU).

Activated six additional clinical trial sites, for a total of eight sites actively screening and enrolling patients, for our Phase 1b/2 multicenter trial of PCM-075 in patients with AML.

Announced that the first patient successfully completed the cycle 1 of treatment in our Phase 1b/2 multicenter trial of PCM-075 in combination with low-dose cytarabine in patients with AML. The patient tolerated the combination well and correlative analyses of blood samples, taken at specified time points, also indicated activity on circulating leukemic cells.

Announced that two additional patients in the initial dose escalation cohort are on treatment and receiving a 12 mg/m² oral, daily dose of PCM-075 (Days 1-5 in a 28-day cycle) in combination with LDAC, completing enrollment of the three patients in this cohort. Additionally, patient enrollment is also complete in the first Phase 1b dose-escalation

cohort of three patients to receive a 12 mg/m² oral, daily dose of PCM-075 (Days 1-5 in a 28-day cycle) in combination with decitabine. Subsequent to this announcement, one patient in the decitabine arm was removed from the trial prior to the end of the 28-day cycle due to unrelated disease progression and will be replaced to complete this dosing cohort.

Presented data showing that PCM-075 exhibits synergistic activity when combined with FLT3 inhibitors in a human xenograft AML model, at the American Association for Cancer Research (“AACR”) Annual Meeting in Chicago, IL.

Presented the methodology developed to track dynamic changes in blood leukemic cells, genomic alterations and PLK1 inhibition in patients treated with PCM-075 in combination with LDAC in its Phase 1b/2 clinical trial in AML, at the AACR Annual Meeting in Chicago, IL.

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

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of March 31, 2018.

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, 2017, filed with the SEC on February 26, 2018. There have been no changes to our critical accounting policies other than adoption of ASC 606 as described in Note 3 to the condensed consolidated financial statements since December 31, 2017.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2018 and 2017

Revenues

Our total revenues were \$100,136 and \$95,038 for the three months ended March 31, 2018 and 2017, respectively. The components of our revenues were as follows:

	Three Months Ended March 31,		
	2018	2017	Increase (Decrease)
Royalties	\$49,055	\$65,826	\$(16,771)
Diagnostic services	40,002	28,862	11,140
Clinical research	11,079	350	10,729
Total revenues	\$100,136	\$95,038	\$5,098

The decrease in royalty income is mainly a result of adoption of ASC 606. Based on the new revenue standards, we recorded approximately \$78,000 to accumulated deficit rather than recognize it to revenue in the first quarter of 2018. See Note 3 to the condensed consolidated financial statements for detailed information. Revenue from diagnostic services is recognized when payment is received for the test results. Payments received was higher in 2018 as compared to the same period in the prior year. Revenue from clinical research consists of revenue from the sale of urine and blood collection supplies and tests performed under agreements with our clinical research and business development partners. Revenue is recognized when control of supplies and/or test results are transferred to customers (upon delivery). There were more sales for the three months ended March 31, 2018 as compared to the same period of 2017.

We expect our royalties to fluctuate as the royalties are sales-based or usage-based royalties on our IP license. Revenue recognition of the royalty depends on the timing and overall sales activities of the licensees. In addition, we expect a decrease in our diagnostic service revenue and clinical research revenue as we focus on develop oncology therapeutics.

Cost of Revenues

Our total cost of revenues was \$366,344 for the three months ended March 31, 2018, compared to \$616,426 in the same period of 2017. Cost of revenues mainly relates to the costs of our diagnostic service revenues. The costs are recognized at the completion of testing. Decrease in cost of revenues for the three months ended March 31, 2018 compared to the same period of last year is mainly due to the lower volume of tests processed.

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Research and Development Expenses

Research and development expenses consisted of the following:

	Three Months Ended March 31,		
	2018	2017	Increase (Decrease)
Salaries and staff costs	\$402,068	\$875,377	\$(473,309)
Stock-based compensation	395,709	372,200	23,509
Outside services, consultants and lab supplies	849,988	634,794	215,194
Facilities	191,391	367,901	(176,510)
Travel and scientific conferences	39,218	16,040	23,178
Fees, license and other	5,464	2,013,518	(2,008,054)
Total research and development	\$1,883,838	\$4,279,830	\$(2,395,992)

Research and development expenses decreased by \$2,395,992 to \$1,883,838 for the three months ended March 31, 2018 from \$4,279,830 for the same period in 2017. Our costs have decreased due primarily to the decreases in fees, license and other and salaries and staff costs. The decrease in fees, license and other was due to the \$2.0 million license fee payment in March 2017 to Nerviano for development and commercialization rights to PCM-075. Our average internal research and development personnel decreased from nineteen to seven, resulting in a decrease of expenses in salaries and staff costs. In addition, as a result of the shifting of our business focus, we entered in new clinical studies related to oncology therapeutics which drove the increase in outside services costs. We expect a reduction of research and development costs that relate to CLIA services; however, other costs may increase as we complete the development of PCM-075.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted of the following:

	Three Months Ended March 31,		
	2018	2017	Increase (Decrease)
Salaries and staff costs	\$690,170	\$1,421,593	\$(731,423)
Board of Directors' fees	128,328	113,619	14,709
Stock-based compensation	970,791	601,309	369,482
Outside services and consultants	191,062	343,620	(152,558)
Legal and accounting fees	163,020	460,682	(297,662)
Facilities and insurance	255,053	269,338	(14,285)
Travel and conferences	56,457	283,933	(227,476)
Fees, license and other	50,096	110,530	(60,434)
Total general and administrative	\$2,504,977	\$3,604,624	\$(1,099,647)

Selling, general and administrative expenses decreased by \$1,099,647 to \$2,504,977 for the three months ended March 31, 2018, from \$3,604,624 for the same period in 2017. The overall decrease in selling, general and administrative expenses was primarily due to the reduction in force. During the three months ended March 31, 2018 we decreased the number of our selling, marketing, and administrative personnel, bringing our average headcount to nine from seventeen in the same period of the prior year. The decrease of selling, general and administrative expenses was offset by an increase in stock-based compensation. 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. Our selling, general and administrative costs may increase in future periods in order to support fundraising activities and general business activities as we continue to develop and introduce new product offerings.

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Restructuring

On March 15, 2017, we announced a strategic restructuring plan in connection with the expansion of precision medicine therapeutics to our business. The restructuring plan included a reduction in force and was completed in the last quarter of 2017. Restructuring charges of approximately \$1.7 million were incurred and had been included as a component of operating loss for the three months ended March 31, 2017.

Net Interest Expense

Net interest expense was \$2,465 and \$429,397 for the three months ended March 31, 2018 and 2017, respectively. The decrease of net interest expense is primarily due to a decrease in interest expense, resulting from pay-off of our \$15.0 million term loan. We expect net interest expense to decrease as a result of repayment of our equipment line of credit.

Change in Fair Value of Derivative Financial Instruments — Warrants

We have issued warrants that are accounted for as derivative liabilities. As of March 31, 2018, the derivative financial instruments—warrants liabilities were revalued to \$779,076, resulting in an increase in value of \$129,689 from December 31, 2017, based primarily upon the increase in our stock price as well as the changes in the expected term, volatility, and risk free interest rates for the expected term. The increase in value was recorded as a loss from the change in fair value of derivative financial instruments—warrants in the condensed consolidated statement of operations.

Net Loss

Net loss and per share amounts were as follows:

	Three Months Ended March 31,		
	2018	2017	Increase (Decrease)
Net loss attributable to common shareholders	\$(4,792,237)	\$(10,005,597)	\$(5,213,360)
Net loss per common share — basic	\$(0.09)	\$(0.32)	\$(0.23)
Net loss per common share — diluted	\$(0.09)	\$(0.32)	\$(0.23)
Weighted average shares outstanding — basic	55,364,438	30,961,014	24,403,424
Weighted average shares outstanding — diluted	55,364,438	30,961,014	24,403,424

The \$5,213,360 decrease in net loss attributable to common shareholders and the \$0.23 decrease in basic net loss per share was primarily the result of a decrease in operating expenses of \$5,465,525 for the three months ended March 31, 2018 compared to the same period in the prior year. Basic net loss per share in 2018 was also impacted by the increase in basic weighted average shares outstanding resulting from the issuance of approximately 6.0 million shares of common stock upon the exercise of warrants as well as vesting of RSU.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2018, we had \$6,657,158 in cash and cash equivalents. Net cash used in operating activities for the three months ended March 31, 2018 was \$2,856,147, compared to \$8,758,208 for the three months ended March 31, 2017. Our use of cash was a result of the net loss of \$4,786,177 for the three months ended March 31, 2018, adjusted for non-cash items related to stock-based compensation of \$1,406,131, depreciation and amortization of \$252,480, deferred rent of \$79,586, and the loss from the change in fair value of derivative financial instruments—warrants of \$129,689. The changes in our operating assets and liabilities consisted of higher accounts

payable and accrued expenses, lower prepaid expenses, as well as decreased accounts receivable and unbilled receivable. At our current and anticipated level of operating loss, we expect to continue to incur an operating cash outflow for the next several years.

Net cash used in investing activities was \$5,100 during the three months ended March 31, 2018, compared to \$5,183,944 provided by investing activities for the same period in 2017. Investing activities during the three months ended March 31, 2018 consisted of net purchases for capital equipment of \$5,100, while investing activities during the three months ended March 31, 2017 consisted primarily of net maturities of short-term investments of \$5,195,396.

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Net cash provided by financing activities was \$1,292,641 during the three months ended March 31, 2018, compared to \$156,526 used in financing activities for the same period in 2017. Financing activities during the three months ended March 31, 2018 related primarily to the proceeds from exercise of warrants of \$1,449,167.

As of March 31, 2018, and December 31, 2017, we had working capital of \$3,985,883 and \$5,522,917, respectively.

Based on our current business plan and assumptions, we expect to continue to incur significant losses and require significant additional capital to further advance our clinical trial programs and support our other operations. Considering our current cash resources, we believe our existing resources will be sufficient to fund our planned operations through July 2018. In addition, we have based our cash sufficiency estimates on our current business plan and assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding to sustain our operations even sooner than currently anticipated. These circumstances raise substantial doubt about our ability to continue as a going concern.

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. To date, our sources of cash have been primarily limited to the sale of equity securities. 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. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates, all of which may have a material adverse impact on our operations. We may also be required to (i) 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 (ii) 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. We are evaluating all options to raise additional capital, increase revenue, as well as reduce costs, in an effort to strengthen our liquidity position, which may include the following: (1) Raising capital through public and private equity offerings; (2) Introducing operation and business development initiatives to bring in new revenue streams; (3) Reducing operating costs by identifying internal synergies; (4) Engaging in strategic partnerships. We continually assess any spending plans, including a review of our discretionary spending in connection with certain strategic contracts, to effectively and efficiently address our liquidity needs.

NASDAQ Notice

On September 5, 2017, we received a written notice from the NASDAQ Stock Market LLC (“NASDAQ”) that we were not in compliance with NASDAQ Listing Rule 5550(a)(2) for continued listing on the NASDAQ Capital Market, as the minimum bid price of our common stock had been below \$1.00 per share for 30 consecutive business days. The Notice had no immediate effect on the listing of our common stock, and our common stock continue to trade on the NASDAQ Capital Market under the symbol “TROV”. In accordance with NASDAQ Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until March 5, 2018, to regain compliance with the minimum bid price requirement.

On March 6, 2018, the NASDAQ Capital Market informed the Company that it is eligible for an additional 180 calendar day period until September 4, 2018 to regain compliance with the minimum \$1.00 bid price per share requirement. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for at least ten consecutive business days during this 180 calendar day period.

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, 2017.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash and cash equivalent primary consists of deposits, and money market deposits managed by commercial banks as of March 31, 2018. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments.

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

We do not believe our cash and cash equivalents have significant risk of default issues; 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.

Foreign Currency Risk

We face the foreign currency risk as a result of entering into transactions denominated in currencies other than U.S. dollars. Changes in foreign currency exchange rates can create foreign exchange gains or losses to us.

Effects of Inflation

We do not believe that inflation and changing prices during the three months ended March 31, 2018 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 principal executive and financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2018 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 March 31, 2018 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 9 to the unaudited Condensed Consolidated Financial Statements for a summary of legal proceedings.

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2017.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit
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<u>31.1</u>	<u>Certification of Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.</u>
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<u>32.1</u>	<u>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.</u>
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101.INS XBRL Instance Document

101.SCH XBRL Taxonomy Extension Schema

101.CAL XBRL Taxonomy Extension Calculation Linkbase

101.LAB XBRL Taxonomy Extension Labels Linkbase

101.PRE XBRL Taxonomy Extension Presentation Linkbase

101.DEF XBRL Taxonomy Extension Definition Linkbase

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SIGNATURES

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

TROVAGENE, INC.

May 8, 2018 By: /s/ William J. Welch

William J. Welch

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