Table of Contents

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

Form 10-Q

(Mark One)

x **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2019

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

For the transition period from to

COMMISSION FILE NUMBER 001-35558

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

Delaware	**27-2004382**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11055 Flintkote Avenue, San Diego, California	**92121**
(Address of principal executive offices)	(Zip Code)

(858) 952-7570
(Registrant's telephone number, including area code)

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	TROV	Nasdaq Capital Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 o	Accelerated filer o	Non-accelerated filer x	Smaller reporting company x	Emerging growth company o

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. o

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

As of October 31, 2019, the issuer had 7,742,355 shares of Common Stock issued and outstanding.

TROVAGENE, INC.

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TROVAGENE, INC.
CONDENSED BALANCE SHEETS
(Unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 9,032,206	$ 11,453,133
Accounts receivable and unbilled receivable	152,038	167,755
Prepaid expenses	792,540	1,144,377
Total current assets	9,976,784	12,765,265
Property and equipment, net	271,401	1,304,433
Operating lease right-of-use assets	1,503,335	—
Other assets	170,943	102,798
Total Assets	$ 11,922,463	$ 14,172,496
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 492,367	$ 664,840
Accrued expenses	2,842,153	1,813,842
Operating lease liabilities	836,294	—
Deferred rent, current portion	—	486,636
Total current liabilities	4,170,814	2,965,318
Derivative financial instruments—warrants	4,956	32,315
Operating lease liabilities, net of current portion	1,090,713	—
Deferred rent, net of current portion	—	1,090,671
Total Liabilities	5,266,483	4,088,304
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.001 par value, 20,000,000 shares authorized; 277,100 designated as Series A Convertible Preferred Stock; 60,600 shares outstanding at September 30, 2019 and December 31, 2018 with liquidation preference of $606,000 at September 30, 2019 and December 31, 2018; 200,000 designated as Series C Convertible Preferred Stock; 0 shares outstanding at September 30, 2019 and December 31, 2018	60	60
Common stock, $0.0001 par value, 150,000,000 shares authorized; 6,436,505 and 3,831,880 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	8,096	7,742
Additional paid-in capital	212,463,077	202,267,605
Service receivables	(1,165,966)	—
Accumulated deficit	(204,649,287)	(192,191,215)
Total stockholders' equity	6,655,980	10,084,192
Total liabilities and stockholders' equity	$ 11,922,463	$ 14,172,496

See accompanying notes to the unaudited condensed financial statements.

TROVAGENE, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Royalties	$ 51,687	$ 72,568	$ 150,560	$ 174,046
Services and other	—	15,793	1,495	126,264
Total revenues	51,687	88,361	152,055	300,310
Costs and expenses:				
Cost of revenues	—	26,677	—	597,457
Research and development	2,818,824	1,830,441	8,297,763	5,667,046
Selling, general and administrative	1,440,339	1,665,200	4,243,490	6,321,048
Restructuring charges	—	421,351	—	664,686
Total operating expenses	4,259,163	3,943,669	12,541,253	13,250,237
Loss from operations	(4,207,476)	(3,855,308)	(12,389,198)	(12,949,927)
Interest income	53,700	85,938	188,204	143,911
Interest expense	—	(16)	—	(25,177)
Gain (loss) from change in fair value of derivative financial instruments—warrants	13,330	(2,500)	27,359	579,040
Gain on extinguishment of debt	—	—	—	17,974
Other income (expense), net	(1,103)	2,318	2,012	(68,521)
Net loss	(4,141,549)	(3,769,568)	(12,171,623)	(12,302,700)
Preferred stock dividend payable on Series A Convertible Preferred Stock	(6,060)	(6,060)	(18,180)	(18,180)
Deemed dividend recognized on beneficial conversion features of Series B Convertible Preferred Stock issuance	—	—	—	(2,769,533)
Deemed dividend recognized on beneficial conversion features of Series C Convertible Preferred Stock issuance	—	—	(268,269)	—
Net loss attributable to common stockholders	$ (4,147,609)	$ (3,775,628)	$ (12,458,072)	$ (15,090,413)
Net loss per common share — basic	$ (0.71)	$ (1.10)	$ (2.46)	$ (8.27)
Net loss per common share — diluted	$ (0.71)	$ (1.10)	$ (2.46)	$ (8.27)
Weighted-average shares outstanding — basic	5,822,818	3,437,100	5,056,794	1,824,208
Weighted-average shares outstanding — diluted	5,822,818	3,437,100	5,056,794	1,824,208

See accompanying notes to the unaudited condensed financial statements.

TROVAGENE, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Service Receivable	Accumulated Deficit	Total Stockholders' Equity
Balance, January 1, 2019	60,600	$ 60	3,831,879	$ 7,742	$202,267,605	$ —	$(192,191,215)	$10,084,192
Stock-based compensation	—	—	—	—	200,067	—	—	200,067
Issuance of common stock, preferred stock and warrants for clinical trial funding commitment, net of expenses and discount of $40,000 and $235,640, respectively	200,000	200	183,334	110	1,634,690	(1,675,000)	—	(40,000)
Deemed dividend recognized on beneficial conversion features of Series C Convertible Preferred Stock issuance	—	—	—	—	268,269	—	(268,269)	—
Issuance of common stock upon exercise of warrants	—	—	497,313	50	3,282,216	—	—	3,282,266
Issuance of common stock upon vesting of restricted stock units	—	—	6,362	4	(4)	—	—	—
Preferred stock dividend payable on Series A Convertible Preferred Stock	—	—	—	—	—	—	(6,060)	(6,060)
Issuance of common stock for share rounding as a result of reverse stock split	—	—	6,466	—	—	—	—	—
Release of clinical trial funding commitment	—	—	—	—	—	70,487	—	70,487
Net loss	—	—	—	—	—	—	(3,904,771)	(3,904,771)
Balance, March 31, 2019	260,600	260	4,525,354	7,906	207,652,843	(1,604,513)	(196,370,315)	9,686,181
Stock-based compensation	—	—	—	—	148,834	—	—	148,834
Sale of common stock and warrants, net of expenses	—	—	421,917	42	2,902,698	—	—	2,902,740
Issuance of common stock upon exercise of warrants	—	—	156,353	16	1,548	—	—	1,564
Issuance of common stock upon vesting of restricted stock units	—	—	4,433	—	—	—	—	—
Issuance of common stock upon conversion of Series C Convertible Preferred Stock	(200,000)	(200)	333,333	33	167	—	—	—
Preferred stock dividend payable on Series A Convertible Preferred Stock	—	—	—	—	—	—	(6,060)	(6,060)
Release of clinical trial funding commitment	—	—	—	—	—	240,279	—	240,279
Net loss	—	—	—	—	—		(4,125,303)	(4,125,303)
Balance, June 30, 2019	60,600	60	5,441,390	7,997	210,706,090	(1,364,234)	(200,501,678)	8,848,235
Stock-based compensation	—	—	—	—	266,325	—	—	266,325
Sale of common stock and warrants, net of expenses	—	—	271,744	27	1,483,554	—	—	1,483,581

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Service Receivable	Accumulated Deficit	Total Stockholders' Equity
Issuance of common stock upon exercise of warrants	—	—	717,969	72	7,108	—	—	7,180
Issuance of common stock upon vesting of restricted stock units	—	—	5,402	—	—	—	—	—
Preferred stock dividend payable on Series A Convertible Preferred Stock	—	—	—	—	—	—	(6,060)	(6,060)
Release of clinical trial funding commitment	—	—	—	—	—	198,268	—	198,268
Net loss	—	—	—	—	—	—	(4,141,549)	(4,141,549)
Balance, September 30, 2019	60,600	$ 60	6,436,505	$ 8,096	$212,463,077	$(1,165,966)	$(204,649,287)	$6,655,980

	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	733,217	$ 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	—	—	71,347	514	1,448,653	—	1,449,167
Issuance of common stock upon vesting of restricted stock units	—	—	12,567	90	(90)	—	—
Preferred stock dividend payable on Series A Convertible Preferred Stock	—	—	—	—	—	(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	817,131	5,883	182,401,648	(177,728,501)	4,679,090
Stock-based compensation	—	—	—	—	221,300	—	221,300
Sale of common stock and warrants, net of expenses	—	—	1,523,333	914	11,778,611	—	11,779,525
Sale of Series B Convertible Preferred Stock, net of expenses	8,860	9	—	—	4,386,753	—	4,386,762
Deemed dividend recognized on beneficial conversion features of Series B Convertible Preferred Stock issuance	—	—	—	—	2,769,533	(2,769,533)	—
Issuance of common stock upon exercise of warrants	—	—	7,570	55	163,445	—	163,500
Issuance of common stock upon conversion of Series B Convertible Preferred Stock	(3,210)	(3)	535,000	321	(318)	—	—
Preferred stock dividend payable on Series A Convertible Preferred Stock	—	—	—	—	—	(6,060)	(6,060)
Issuance of common stock for share rounding as a result of reverse stock split	—	—	1,134	—	—	—	—
Net loss	—	—	—	—	—	(3,746,955)	(3,746,955)
Balance, June 30, 2018	66,250	66	2,884,168	7,173	201,720,972	(184,251,049)	17,477,162
Stock-based compensation	—	—	—	—	278,221	—	278,221
Preferred stock dividend	—	—	—	—	—	(6,060)	(6,060)
Issuance of common stock upon conversion of Series B Convertible Preferred Stock	(5,650)	(6)	941,667	565	(559)	—	—
Issuance of common stock upon vesting of restricted stock units	—	—	362	—	—	—	—
Issuance of common stock for share rounding as a result of reverse stock split	—	—	2	—	—	—	—
Net loss	—	—	—	—	—	(3,769,568)	(3,769,568)
Balance, September 30, 2018	60,600	$ 60	3,826,199	$ 7,738	$201,998,634	$(188,026,677)	$13,979,755

See accompanying notes to the unaudited condensed financial statements.

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

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (12,171,623)	$ (12,302,700)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of assets	—	197,490
Impairment loss	—	187,500
Depreciation and amortization	130,219	701,774
Stock-based compensation expense	615,226	1,905,652
Gain on extinguishment of debt	—	(17,974)
Deferred rent	—	(266,556)
Change in fair value of derivative financial instruments—warrants	(27,359)	(579,040)
Release of clinical trial funding commitment	509,034	—
Changes in operating assets and liabilities:		
Other assets	(68,145)	(170,602)
Accounts receivable and unbilled receivable	15,717	58,440
Prepaid expenses	277,876	316,746
Operating lease right-of-use assets	467,009	—
Accounts payable and accrued expenses	837,551	383,037
Operating lease liabilities	(576,141)	—
Net cash used in operating activities	(9,990,636)	(9,586,233)
Investing activities:		
Proceeds from disposals of capital equipment	—	27,942
Capital expenditures	(67,622)	(5,100)
Purchases of short-term investments	—	(31,500)
Sales of short-term investments	—	31,500
Net cash used in investing activities	(67,622)	22,842
Financing activities:		
Proceeds from sales of common stock and warrants, net of expenses of $113,678 and $1,336,123, respectively	4,386,321	11,779,525
Proceeds from sales of Series B Convertible Preferred Stock, net of expenses of $497,617	—	4,386,762
Costs related to the clinical trial funding commitment	(40,000)	—
Proceeds from exercise of warrants	3,291,010	1,612,667
Payment upon debt extinguishment	—	(175,381)
Repayments of equipment line of credit	—	(1,200,033)
Net cash provided by financing activities	7,637,331	16,403,540
Net change in cash and cash equivalents	(2,420,927)	6,840,149
Cash and cash equivalents—Beginning of period	11,453,133	8,225,764
Cash and cash equivalents—End of period	$ 9,032,206	$ 15,065,913
Supplementary disclosure of cash flow activity:		
Cash paid for taxes	$ 800	$ 800
Cash paid for interest	$ —	$ 22,482

	Nine Months Ended September 30,	
	2019	2018
Supplemental disclosure of non-cash investing and financing activities:		
Preferred stock dividend payable on Series A Convertible Preferred Stock	$ 18,180	$ 18,180
Deemed dividend recognized for beneficial conversion features of Series B Convertible Preferred Stock issuance	$ —	$ 2,769,533
Deemed dividend recognized for beneficial conversion features of Series C Convertible Preferred Stock issuance	$ 268,269	$ —
Common stock, Series C Convertible Preferred Stock and warrants issued in connection with clinical trial funding commitment, net of discount of $235,640	$ 1,675,000	$ —
Common stock issued upon conversion of Series B Convertible Preferred Stock	$ —	$ 886
Common stock issued upon conversion of Series C Convertible Preferred Stock	$ 33	$ —

See accompanying notes to the unaudited condensed financial statements.

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

1. Organization and Basis of Presentation

Business Organization and Overview

Trovagene, Inc. ("Trovagene" or the "Company") headquartered in San Diego, California, is a clinical-stage, oncology therapeutics company, taking a Precision Cancer Medicine™ (PCM) approach to develop drugs that target mitosis (cell division) to treat various types of cancer, including prostate, colorectal and leukemia. By integrating a biomarker strategy into our development programs, we will be able to identify patients more likely to respond to treatment.

Trovagene's intellectual property portfolio and proprietary technology includes the exclusive world-wide license of 3 issued patents for onvansertib which cover composition of matter, salt forms of onvansertib and combination of onvansertib with other drugs.

Basis of Presentation

The accompanying unaudited interim condensed financial statements of Trovagene have been prepared in accordance with accounting principles generally accepted in the United States of America ("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 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, 2018 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 financial statements are not necessarily indicative of the results that may be expected for any future periods. These unaudited interim condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended December 31, 2018 included in the Company's annual report on Form 10-K filed with the SEC on March 6, 2019.

The Company made a reverse split of its common stock, $0.0001 par value, at a ratio of 1 for 6, effective February 19, 2019. All share and per share information in the unaudited condensed financial statements and the accompanying notes have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Liquidity

Trovagene's condensed financial statements as of September 30, 2019 have been prepared under the assumption that Trovagene 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, and service receivable related to the clinical trial funding commitment, management projects the Company's existing resources will be sufficient to fund the Company's planned operations into the third quarter of 2020. 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 the following options to raise additional capital, increase revenue, as well as reduce costs, in an effort to strengthen its liquidity position:

- 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 September 30, 2019, the Company has received approximately $3.3 million upon exercise of 497,313 warrants in connection with the June 2018 underwritten public offering. The Company has also received approximately $4.4 million from proceeds from the sale of common stock and warrants, net of expenses. The Company also received $1.7 million through a private placement for funding of the Company's clinical trials. The Company continually assesses its spending plans to effectively and efficiently address its liquidity needs.

2. Summary of Significant Accounting Policies

During the nine months ended September 30, 2019, 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, 2018, except as described below.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, current operating lease liabilities and non-current operating lease liabilities in the Company's balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company's operating leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The incremental borrowing rate is the rate of interest that the Company would expect to pay to borrow on a collateralized and fully amortizing basis over a similar term an amount equal to the lease payments in a similar economic environment. The operating lease ROU asset also includes any lease payments made less lease incentives received. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense is recognized on a straight-line basis over the lease term. Our facilities lease agreement contain lease and non-lease components, such as common area maintenance. We have elected to account for these lease and non-lease components of these agreements as a single lease component.

Leases with an initial term of 12 months or less are not recorded on the Company's balance sheets. These short-term leases are expensed on a straight-line basis over the lease term.

Net Loss Per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator: Net loss attributable to common shareholders	$ (4,147,609)	$ (3,775,628)	$ (12,458,072)	$ (15,090,413)
Net loss used for diluted loss per share	$ (4,147,609)	$ (3,775,628)	$ (12,458,072)	$ (15,090,413)
Denominator for basic and diluted net loss per share:				
Weighted-average shares used to compute basic loss per share	5,822,818	3,437,100	5,056,794	1,824,208
Weighted-average shares used to compute diluted net loss per share	5,822,818	3,437,100	5,056,794	1,824,208
Net loss per share attributable to common stockholders:				
Basic	$ (0.71)	$ (1.10)	$ (2.46)	$ (8.27)
Diluted	$ (0.71)	$ (1.10)	$ (2.46)	$ (8.27)

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

	September 30,	
	2019	2018
Options to purchase Common Stock	1,016,426	83,375
Warrants to purchase Common Stock	4,870,076	3,698,256
Restricted Stock Units	14,161	35,812
Series A Convertible Preferred Stock	877	877
	5,901,540	3,818,320

Recently Adopted Accounting Pronouncement

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 changes accounting for leases and requires lessees to recognize the assets and liabilities arising from most leases, including those classified as operating leases under previous accounting guidance, on the balance sheet and requires disclosure of key information about leasing arrangements to increase transparency and comparability among organizations. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842*, which provides narrow amendments to clarify how to apply certain aspects of the new lease standard. In July 2018, ASU 2018-11, *Leases: Targeted Improvements*, was issued to provide relief to companies from restating comparative periods. Pursuant to this ASU, in the period of adoption the Company will not restate comparative periods presented in its financial statements.

The Company adopted ASU 2016-02 in the first quarter of 2019 utilizing the modified retrospective transition method through a cumulative-effect adjustment at the beginning of the first quarter of 2019 and did not restate comparative periods. The Company has elected the package of practical expedients, which allows the Company not to reassess (1) whether any expired or existing contracts as of the adoption date are or contain a lease, (2) lease classification for any expired or existing leases as of the adoption date and (3) initial direct costs for any existing leases as of the adoption date. The Company did not elect to apply the hindsight practical expedient when determining lease term and assessing impairment of right-of-use assets. The adoption of ASU 2016-02 on January 1, 2019 resulted in the recognition of right-of-use assets of approximately $1,970,000

and lease liabilities for operating leases of approximately $2,503,000. There was no cumulative effect adjustment to accumulated deficit as a result of the adoption and there was not a material impact to the Company's consolidated statement of operations. Refer to Note 5 to the condensed financial statements for further details.

Recent Accounting Pronouncement Not Yet Adopted

In August 2018, the FASB issued ASU No. 2018-13, *Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. The standard is effective for all entities for financial statements issued for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The adoption of this guidance is not expected to have a material impact on the Company's financial statements.

3. Fair Value Measurements

The following table presents the Company's assets and liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of September 30, 2019 and December 31, 2018:

	Fair Value Measurements at September 30, 2019			
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market fund (1)	$ 8,965,312	$ —	$ —	$ 8,965,312
Total Assets	$ 8,965,312	$ —	$ —	$ 8,965,312
Liabilities:				
Derivative financial instruments—warrants	$ —	$ —	$ 4,956	$ 4,956
Total Liabilities	$ —	$ —	$ 4,956	$ 4,956

	Fair Value Measurements at December 31, 2018			
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market fund (1)	$ 11,392,093	$ —	$ —	$ 11,392,093
Total Assets	$ 11,392,093	$ —	$ —	$ 11,392,093
Liabilities:				
Derivative financial instruments—warrants	$ —	$ —	$ 32,315	$ 32,315
Total Liabilities	$ —	$ —	$ 32,315	$ 32,315

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

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the nine months ended September 30, 2019:

Description	Balance at December 31, 2018	Realized (gains) or losses	Balance at September 30, 2019
Derivative financial instruments—warrants	$ 32,315	$ (27,359)	$ 4,956

The change in the fair value of the "derivative financial instruments—warrants" is recorded as a gain or loss in the Company's 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.

4. Property and Equipment

Property and equipment consist of the following:

	As of September 30, 2019	As of December 31, 2018
Furniture and office equipment	$ 775,030	$ 775,030
Leasehold improvements	102,230	1,962,230
Laboratory equipment	744,856	677,234
	1,622,116	3,414,494
Less—accumulated depreciation and amortization	(1,350,715)	(2,110,061)
Property and equipment, net	$ 271,401	$ 1,304,433

5. Leases

As a lessee, the Company's current leases include its master facility lease and immaterial equipment leases, all of which are considered operating leases.

The Company (as a sublessor) also subleases portions of its facility to third parties under three separate subleases. All of these subleases have been determined to be operating leases and are accounted for separately from the head lease.

Master Facility Lease

The Company leases a building in San Diego under an operating lease that expires on December 31, 2021. The lease currently requires fixed monthly rent payments of approximately $76,000, with 3% annual escalation. The lease also contains one five-year renewal option with minimum monthly rent equal to the then-current fair market value, subject to a 3% annual increase. As the Company is not reasonably certain to exercise this option, it has not been included in the calculation of the lease liability or right-of-use asset related to this lease.

Facility Subleases

As a result of corporate restructurings in previous years, the Company vacated a portion of its facility and has subleased the space to third parties under three separate sublease agreements, including one that expires October 31, 2019 and two that expire December 31, 2021. Under the new standard, ROU assets and lease liabilities are not required to be established on the Company's balance sheet for such operating subleases. The Company recorded a cease-use loss liability and expense in 2018 pursuant to ASC 420, *Exit or Disposal Cost Obligations*, representing the total expected shortfall in sublease income for two of the subleases as compared to its required payments for those spaces under the remainder of the master lease term. This liability was being amortized over the remaining lease term until the adoption of ASC 842, whereupon the remaining cease-use loss liability of approximately $487,000 was eliminated and treated as a reduction to the beginning ROU asset value for the master lease as of January 1, 2019. Income will continue to be recognized on a straight-line basis over the term of the sublease.

The components of lease expense were as follows:

	Three months ended September 30, 2019	Nine Months Ended September 30, 2019
Operating lease cost	$ 191,472	$ 578,919
Operating sublease income	(99,937)	(299,812)
Net operating lease cost	$ 91,535	$ 279,107

Supplemental balance sheet information related to leases was as follows:

	September 30, 2019
Operating lease ROU assets	$ 1,503,335
Current operating lease liabilities	$ 836,294
Non-current operating lease liabilities	1,090,713
Total operating lease liabilities	$ 1,927,007
Weighted-average remaining lease term–operating leases	2.3 years
Weighted-average discount rate–operating leases	6.5%

Supplemental cash flow and other information related to leases was as follows:

	Three months ended September 30, 2019	Nine Months Ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 229,927	$ 685,865
ROU assets obtained in exchange for lease obligations:		
Operating leases	$ —	$ 2,503,148

Total remaining annual commitments under non-cancelable lease agreements for each of the years ended December 31 are as follows:

Year Ending December 31,	Operating Leases	Sublease Income	Net Operating Leases
2019 (excluding the nine months ended September 30, 2019)	$ 154,606	$ (81,841)	$ 72,765
2020	941,670	(291,173)	650,497
2021	968,165	(291,173)	676,992
2022	5,868	—	5,868
2023	3,423	—	3,423
Total future minimum lease payments	2,073,732	$ (664,187)	$ 1,409,545
Less imputed interest	(146,725)		
Total	$ 1,927,007		

Total annual commitments under non-cancelable lease agreements as of December 31, 2018 under the previous lease accounting guidance are as follows:

	Operating Leases	Sublease Income	Net Operating Leases
2019	$ 914,540	$ (333,124)	$ 581,416
2020	941,670	—	941,670
2021	968,165	—	968,165
2022	5,868	—	5,868
2023	3,423	—	3,423
Total	$ 2,833,666	$ (333,124)	$ 2,500,542

6. Derivative Financial Instruments — Warrants

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, *Contracts in Entity's Own Equity* ("ASC 815-40") or ASC Topic 480-10, *Distinguishing Liabilities from Equity* ("ASC 480-10"), Trovagene determined that certain warrants issued in connection with the execution of certain equity financings must be recorded as derivative liabilities. In accordance with ASC 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 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 were:

	Nine Months Ended September 30,	
	2019	**2018**
Estimated fair value of Trovagene common stock	1.51-3.75	4.62-25.20
Expected warrant term	3.3-4.1 years	0.3-5.1 years
Risk-free interest rate	1.56-2.49%	1.76-2.92%
Expected volatility	102-106%	47-131%
Dividend yield	0%	0%

Expected volatility is based on historical volatility of Trovagene'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, Trovagene 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, 2018	Balance of derivative financial instruments—warrants liability	64,496	$ 32,315
	Change in fair value of derivative financial instruments—warrants during the period recognized as a gain in the condensed statements of operations	—	(27,359)
September 30, 2019	Balance of derivative financial instruments—warrants liability	64,496	$ 4,956

7. Stockholders' Equity

Common Stock

During the nine months ended September 30, 2019, the Company issued a total of 2,604,626 shares of Common Stock. The Company issued 183,334 shares of its common stock, 150,000 warrants, and 200,000 shares of Series C Convertible Preferred Stock through a private placement in January 2019 to PoC Capital, LLC ("PoC") in exchange for funding the Company's clinical trials in the aggregate amount of $1.7 million. The Company also received gross proceeds of $4.5 million from the sale of 693,661 shares of its common stock, 1,567,983 warrants, and 874,322 pre-funded warrants through registered direct offerings and private placements in April, May and August 2019. 497,313 shares were issued upon exercise of warrants for a weighted-average price of $6.60. 16,197 shares were issued upon vesting of restricted stock units ("RSUs"). 333,333 shares were issued upon conversion of Series C Convertible Preferred Stock. In addition, 6,466 shares were issued for share rounding as a result of the reverse stock split.

Stock Options

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Included in cost of revenue	$ —	$ —	$ —	$ 30,488
Included in research and development expense	104,152	130,300	300,291	637,821
Included in selling, general and administrative expense	162,172	147,921	314,935	1,237,343
Total stock-based compensation expense	$ 266,324	$ 278,221	$ 615,226	$ 1,905,652

The unrecognized compensation cost related to non-vested stock options outstanding at September 30, 2019 and 2018, net of expected forfeitures, was $1,476,725 and $499,861, respectively, which is expected to be recognized over a weighted-average remaining vesting period of 2.4 and 1.3 years, respectively. The weighted-average remaining contractual term of outstanding options as of September 30, 2019 was approximately 9.4 years. The total fair value of stock options vested during the nine months ended September 30, 2019 and 2018 were $321,870 and $1,515,946, 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:

	Nine Months Ended September 30,	
	2019	2018
Risk-free interest rate	1.8%	2.5%
Dividend yield	0%	0%
Expected volatility	95.5%	91%
Expected term	5.9 years	5.2 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, 2018	83,345	$ 146.09	$ —
Granted	971,313	$ 2.49	
Canceled / Forfeited	(36,148)	$ 26.55	
Expired	(2,084)	$ 216.00	
Balance outstanding, September 30, 2019	1,016,426	$ 12.98	$ —
Exercisable at September 30, 2019	72,224	$ 147.79	$ —

On June 6, 2019, the number of authorized shares in the Trovagene 2014 Equity Incentive Plan (“2014 EIP”) was increased from 243,056 to 1,243,056. As of September 30, 2019, there were 170,888 shares available for issuance under the 2014 EIP.

Restricted Stock Units

The weighted-average grant date fair value of the RSUs was $1.71 and $4.62 per share during the nine months ended September 30, 2019 and 2018, respectively.

A summary of the RSU activity is presented below:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Intrinsic Value
Non-vested RSUs outstanding, December 31, 2018	30,132	$ 14.36	$ 95,005
Granted	6,167	$ 1.71	
Vested	(16,197)	$ 10.47	$ 53,947
Forfeited	(5,941)	$ 13.82	
Non-vested RSUs outstanding, September 30, 2019	14,161	$ 13.52	$ 21,383

At September 30, 2019, total unrecognized compensation cost related to non-vested RSUs was $93,234, which is expected to be recognized over a weighted-average period of 1.1 years. The total fair value of vested RSUs during the nine months ended September 30, 2019 and 2018 were $169,563 and $1,072,741, respectively.

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, 2018	3,649,341	$ 8.91	4.4
Granted	2,592,370	$ 2.81	
Exercised	(1,371,635)	$ 4.15	
Balance outstanding, September 30, 2019	4,870,076	$ 7.00	4.2

Series C Convertible Preferred Stock

On January 25, 2019, the Company entered into a Master Services Agreement and a Stock and Warrant Subscription Agreement with PoC, whereby PoC agreed to finance $1.675 million in clinical studies, including the development costs associated with Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin® in patients with metastatic Colorectal Cancer (“mCRC”) harboring KRAS mutation in exchange for (i)183,334 shares of common stock, (ii) warrants to purchase an aggregate of 150,000 shares of common stock, with an exercise price of $3.762 per share, expiring on January 25, 2024, and (iii) 200,000 shares of Series C Convertible Preferred Stock, each share of which was convertible into 1.67 shares of common stock. In April of 2019, all 200,000 shares of Series C Convertible Preferred Stock were converted into 333,333 shares of the Company's common stock. As of September 30, 2019, there were no shares of Series C Convertible Preferred Stock outstanding.

The Company evaluated the awards issued under this transaction and determined they should be classified as equity. These equity awards were fully vested and nonforfeitable. Since the equity awards were for clinical trial services yet to be provided, the Company recognized $1.675 million service receivables as contra equity. The Company releases the service receivables as clinical trial services are performed. The conversion feature of the Series C Convertible Preferred Stock at the time of issuance was determined to be beneficial on the commitment date. Because the Series C Convertible Preferred Stock was perpetual with no stated maturity date, and the conversions could occur any time from inception, the Company immediately recorded a non-cash deemed dividend of $0.3 million related to the beneficial conversion feature arising from the issuance of Series C Convertible Preferred Stock. This non-cash deemed dividend increased the Company’s net loss attributable to common stockholders and net loss per share.

The holders of Series C Convertible Preferred Stock were granted the right to vote, on an as-converted to common stock basis (limited to 93.41% of the then as-if converted common stock) all matters submitted to a vote of holders of the Company’s common stockholders. In the event of liquidation, dissolution or winding-up, holders of Series C Convertible Preferred Stock were entitled to receive the same amount that a holder of the Company’s common stock would receive if the Series C Convertible Preferred Stock were fully converted into shares of the Company’s common stock at the conversion price which amounts shall be paid *pari passu* with all holders of common stock.

8. 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.

Research and Development and Clinical Trial 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 Trovagene refers to as onvansertib. Onvansertib is an oral, investigative drug and a highly-selective adenosine triphosphate competitive inhibitor of the serine/threonine PLK1. The Company plans to develop onvansertib in patients with leukemias/lymphomas 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. Under the agreement, the Company is committed to purchase $1.0 million for services provided by Nerviano, such as service for manufacturing drug product, no later than June 30, 2019. As of September 30, 2019, services in excess of $1.0 million have been ordered in full satisfaction of this obligation. 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 and oncology therapeutics. License fees are generally calculated as a percentage of product revenues, with rates that vary by agreement. To date, payments have not been material.

Litigation

Trovagene does not believe that it 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.

9. Related Party Transactions

In November 2018, the Company entered into a Material Transfer Agreement ("MTA") with Leucadia Life Sciences ("Leucadia") pursuant to which Leucadia will develop a PCR-based assay for onvansertib for Acute Myeloid Leukemia ("AML"). In May 2019, the MTA was amended and increased to $1,070,000 to account for additional deliverables in development of the PCR-based assay. The Company's CEO, Dr. Thomas Adams, is a principal stockholder of Leucadia. In addition, in connection with the MTA, the Company entered into a consulting agreement with Tommy Adams, VP of Operations of Leucadia, who is the son of Dr. Adams. During the nine months ended September 30, 2019, the Company incurred and recorded approximately $745,000 of research and development expenses for services performed by Leucadia and Tommy Adams.

10. Subsequent Event

On October 30, 2019, we closed a private placement with certain institutional investors for gross proceeds of approximately $5.0 million. We sold an aggregate of 2,756,340 shares of common stock (including common stock equivalents) and Series G and Series H Warrants to purchase 2,756,340 shares of Common Stock for each class of Warrant. The Securities were sold at a price of $1.814 per Share.

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, 2018, filed on March 6, 2019. 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, taking a Precision Cancer Medicine™ (PCM) approach to develop drugs that target mitosis (cell division) to treat various types of cancer, including prostate, colorectal and leukemia. By integrating a biomarker strategy into our development programs, we will be able to identify patients more likely to respond to treatment.

On March 15, 2017, we announced that we licensed onvansertib, a PLK1 inhibitor, from Nerviano, pursuant to a license agreement with Nerviano dated March 13, 2017. This exclusive, world-wide license agreement includes 3 issued patents for onvansertib which cover composition of matter, salt forms of onvansertib and combination of onvansertib with other drugs. Onvansertib was developed to have high selectivity to PLK1 (at low nanomolar IC_{50} levels), to have ideal pharmacokinetics, including oral bioavailability and administration and a drug half-life of approximately 24 hours, allowing for flexible dosing and scheduling, and is well tolerated and safe with only mild to moderate side effects reported to-date. A Phase 1 safety study of onvansertib has been successfully completed in patients with advanced metastatic solid tumors and published in 2017 in *Investigational New Drugs.*

We currently have three active clinical trials: a Phase 2 open-label clinical trial of onvansertib in combination with abiraterone acetate (Zytiga®) and prednisone in patients with metastatic Castration-Resistant Prostate Cancer ("mCRPC"), being conducted at Beth Israel Deaconess Medical Center ("BIDMC"), Dana-Farber Cancer Institute ("DFCI"), and Massachusetts General Hospital ("MGH"); a Phase 1b/2 open-label clinical trial of onvansertib in combination with FOLFIRI and Avastin® in patients with mCRC with a KRAS mutation, being conducted at USC Norris Comprehensive Cancer Center and The Mayo Clinic; and a Phase 1b/2 open-label clinical trial of onvansertib in combination with standard-of-care chemotherapy in patients with AML, being conducted at eight sites across the U.S.

Onvansertib is a first-in-class, third-generation, oral and highly-selective PLK1 inhibitor with demonstrated antitumor activity in different preclinical models. 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. The over-expression 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 leukemias/lymphomas and solid tumor cancers, including acute myeloid leukemia, non-Hodgkin lymphoma, prostate, lung, breast, ovarian, colorectal and adrenocortical carcinoma. In addition, several studies have shown that over-expression of PLK1 is associated with poor prognosis. Blocking the expression of PLK1 by kinase inhibitors, such as onvansertib, can effectively inhibit growth of, and induce, tumor cell death.

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 prior PLK inhibitor of up to 31% were observed when used in conjunction with a standard therapy for AML (low-dose cytarabine ("LDAC")) versus a 13.3% response rate with LDAC alone. We believe the more selective nature of onvansertib to PLK1, its 24-hour half-life and oral bioavailability, as well as its demonstrated safety and tolerability, with expected on-target, easy to manage and reversible side effects, may prove useful in addressing clinical therapeutic needs across a variety of cancers.

Onvansertib 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. Onvansertib has been tested for antiproliferative activity on a panel of 148 tumor cell lines and appeared highly active with an IC_{50} (a measure concentration for 50% target inhibition) below 100 nM in 75 cell lines and IC_{50} values below 1 uM in 133 out of 148 cell lines. Onvansertib also appears active in cells expressing multi-drug resistant ("MDR") transporter proteins and we believe its apparent ability to overcome the MDR transporter resistance mechanism in cancer cells could prove useful in broader drug combination applications.

In in-vitro and in-vivo 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 onvansertib when used in combination with numerous different chemotherapies, including cisplatin, cytarabine, doxorubicin, gemcitabine and paclitaxel, as well as targeted therapeutics, such as abiraterone acetate (Zytiga®), histone deacetylase ("HDAC") inhibitors, such as belinostat (Beleodaq®), quizartinib (AC220), a development stage FLT3 inhibitor, and bortezomib (Velcade®). These therapies are used clinically for the treatment of leukemias, lymphomas and solid tumor cancers, including AML, Non-Hodgkin Lymphoma ("NHL"), mCRPC, mCRC, and Triple Negative Breast Cancer ("TNBC").

We continue to focus on advancing our three active clinical trials with onvansertib in 2019. We have achieved a number of key milestones through the first three quarters of 2019 and anticipate achieving additional milestones through the end of 2019:

Phase 2 Trial of Onvansertib in Combination with Abiraterone Acetate (Zytiga®) and Prednisone for the Treatment of Metastatic Castration-Resistant Prostate Cancer

- Completed enrollment and evaluation of the 6 safety lead-in patients in the second arm (2-week dosing schedule) with onvansertib at 24 mg/m^2 in combination with abiraterone acetate (Zytiga®) and prednisone.
- Provide safety and preliminary efficacy data of onvansertib in combination with abiraterone acetate (Zytiga®) and prednisone in patients treated through the end of 2019.
- Present data from the mCRPC trial at key oncology conferences throughout 2019, including the Asia-Pacific Prostate Cancer Conference ("APPC"), and first quarter of 2020 including ASCO-GU.

Phase 1b/2 Trial of Onvansertib in Combination with FOLFIRI and Bevacizumab (Avastin®) for Second-Line Treatment of Metastatic Colorectal Cancer with a KRAS Mutation

- Completed enrollment and evaluation of the initial dose level cohort of onvansertib 12 mg/m^2 and opened the second dose level (onvansertib 15 mg/m^2) cohort to enrollment.
- Provide safety and preliminary efficacy data on the combination of onvansertib + FOLFIRI + Avastin® in patients treated through the end of 2019.

Phase 1b/2 Trial of Onvansertib in Combination with Either Low-Dose Cytarabine or Decitabine for the Treatment of Acute Myeloid Leukemia

- Completed Phase 1b dose escalation safety segment of trial, identified the recommended Phase 2 dose (“RP2D”) of onvansertib at 60mg/m^2.
- Initiated the Phase 2 segment of the AML trial, which will enroll approximately 32 patients, for continued evaluation of safety and efficacy of onvansertib in combination with decitabine.
- Provide safety and preliminary efficacy data on the combination of onvansertib in combination with decitabine in patients treated through the end of 2019.
- Present data from the AML trial at key oncology conferences, including the European Society for Medical Oncology ("ESMO") and the American Society of Hematology (“ASH”) annual meetings.

During 2019, we advanced our business with the following activities:

- Announced positive response to treatment in Phase 1b/2 trial of onvansertib in patients with KRAS-mutated metastatic colorectal cancer.

  On October 22, 2019, we announced data demonstrating positive response to treatment in patients enrolled in our Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin (bevacizumab) for second-line treatment of KRAS-mutated metastatic colorectal cancer ("mCRC"). Decreases in tumor KRAS mutational burden in response to treatment with onvansertib was observed in all four patients who completed their first cycle of therapy, as measured by quantitative analysis of circulating tumor DNA (ctDNA).

- Announced data presented at ESMO providing rationale for a clinical trial of onvansertib in subset of patients with Highly-Aggressive Triple Negative Breast Cancer (TNBC).

  On October 2, 2019, we announced the presentation of data in a poster at ESMO demonstrating significant tumor regression observed with onvansertib in combination with standard-of-care paclitaxel in models of p53-mutated TNBC. Onvansertib preclinical data provides rationale for conducting a clinical trial targeting the 80% of TNBC that harbors the p53 mutation. The combination has potential to address critical medical need to provide targeted treatment option to overcome resistance to paclitaxel as single agent therapy in TNBC.

- Announced presentation of a poster at ESMO of Phase 1b/2 trial of onvansertib in patients with KRAS-mutated mCRC.

  On October 1, 2019, we announced the presentation of a poster at ESMO providing an overview of our Phase 1b/2 trial in metastatic Colorectal Cancer, to assess the safety and efficacy of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) in KRAS-mutated mCRC. Approximately 50% of patients harbor the KRAS mutation; current standard-of-care therapy has only a 5% response rate. Biomarker data demonstrates ability to assess patient response to therapy within one week of treatment with onvansertib.

- Announced Oral Presentation of Positive Data from Trovagene Phase 1b/2 Study of Onvansertib at ESMO Conference.

  On September 30, 2019, we announced positive data from our Phase 1b/2 trial in AML which was presented in an oral plenary session at the ESMO conference. The data showed that administration of onvansertib in combination with standard-of-care chemotherapy is safe and well-tolerated and resulted in anti-leukemic activity that appears to be sustainable over time. There is a strong correlation between biomarker positive patients and treatment response; observed in 6 of 9 biomarker positive patients versus 1 of 11 biomarker negative patients. Phase 2 is open to enrolling 32 patients for treatment with onvansertib at the recommended dose of 60 mg/m², in combination with decitabine, to further assess safety and efficacy of the regimen.

- Announced Successful Completion of the AML Phase 1b Trial and Initiation of the Phase 2 Continuation Trial.

  On September 19, 2019, we announced the successful completion of our Phase 1b trial in AML and the initiation of patient enrollment in Phase 2. The Phase 1b dose escalation clinical trial confirmed safety, preliminary efficacy and identified the recommended phase 2 dose of onvansertib. Complete response (CR + CRi) was achieved in 5 of 21 patients treated with onvansertib in combination with decitabine. Phase 2 will treat 32 patients with onvansertib + decitabine; eligible patients will have relapsed after receiving up to one prior therapy including patients who have developed resistance to first-line treatment with venetoclax.

- Announced the Presentation of Positive Clinical Data from Ongoing Phase 2 Study of Onvansertib in mCRPC at the Asia-Pacific Prostate Cancer Conference.

  On August 26, 2019, we announced findings from our Phase 2 trial in mCRPC that leads to the discovery that onvansertib stops the rise in PSA in patients with treatment-resistant, highly-aggressive and difficult-to-treat androgen-receptor variant 7 (AR-V7) tumors. Data demonstrates efficacy of onvansertib in patients showing early signs of resistance to androgen receptor signaling (ARS) inhibitor, Zytiga®. The addition of onvansertib appears to extend the duration of response to ARS inhibitor therapy in this incurable and lethal cancer.

- Announced research collaboration with Nektar Therapeutics to evaluate the efficacy of the combination of onvansertib and ONZEALD™ in models of colorectal cancer.

  On May 23, 2019, we announced we entered into a research collaboration agreement with Nektar Therapeutics to explore the combination of our PLK1 inhibitor, onvansertib, and Nektar's topoisomerase I inhibitor, ONZEALD, for the treatment of mCRC. Under the collaboration, the two companies will evaluate the antitumor activity and tolerability of the combination of onvansertib and ONZEALD in two (HT29 - BRAF mutant and HCT-116 - KRAS mutant) preclinical tumor models of colorectal cancer.

- Announced Data Demonstrating Significant Synergy of Onvansertib in Combination with Venetoclax in Cell Model of Venetoclax-Resistant AML.

  On April 23, 2019, we announced preclinical data that evaluated the effect of combining onvansertib with venetoclax in an AML cell model known to be resistant to venetoclax (Venclexta® - AbbVie). This combination demonstrated synergy (the combined effect of the two drugs is greater than the sum of their individual effects) with a significant decrease in tumor cell viability. This data provides support for clinical evaluation of onvansertib in combination with venetoclax in patients with difficult-to-treat relapsed/refractory AML, for which there are limited treatment options and the prognosis is poor.

- Announced New Patent Issued for Combination of Onvansertib with Anti-Androgen Drugs to Treat Non-Metastatic and Metastatic Prostate Cancer.

  On January 23, 2019, we announced the issuance of a new patent (10,155,006), entitled *Combination Therapies and Methods of Use Thereof for Treating Cancer,* by the U.S. Patent and Trademark Office ("USPTO"). This patent broadens previously issued patent (9,566,280), by expanding the use of onvansertib to encompass combination therapies with any anti-androgen and androgen antagonist drug, such as Zytiga®, Xtandi® and Erleada® for the treatment of metastatic and non-metastatic castrate-resistant prostate cancer.

Our accumulated deficit through September 30, 2019 is $204,649,287. To date, we have generated minimal revenues and expect to incur additional losses to perform further research and development activities.

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 September 30, 2019.

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, 2018, filed with the SEC on March 6, 2019. There have been no changes to our critical accounting policies other than adoption of ASC 842 since December 31, 2018.

RESULTS OF OPERATIONS

Three Months Ended September 30, 2019 and 2018

Revenues

Our total revenues were $51,687 and $88,361 for the three months ended September 30, 2019 and 2018, respectively. The components of our revenues were as follows:

	Three Months Ended September 30,		
	2019	2018	Increase (Decrease)
Royalties	$ 51,687	$ 72,568	$ (20,881)
Services and other	—	15,793	(15,793)
Total revenues	$ 51,687	$ 88,361	$ (36,674)

The decrease in royalty income related primarily to a reduction to the accrual rate. The decrease in service and other revenue for the three months ended September 30, 2019 as compared to the prior period is primarily from the disposition of our CLIA laboratory. We expect our royalties to fluctuate as the royalties are sales-based or usage-based royalties on our intellectual property license. Revenue recognition of the royalty depends on the timing and overall sales activities of the licensees.

Cost of Revenues

Our total cost of revenues was $0 for the three months ended September 30, 2019, compared to $26,677 in the same period of 2018. Cost of revenues relates to the costs of our diagnostic service revenues. The decrease in cost of revenues for the three months ended September 30, 2019 compared to the same period of last year is mainly due to the disposition of our CLIA laboratory. We do not expect any cost of revenue based on our current business model.

Research and Development Expenses

Research and development expenses consisted of the following:

	Three Months Ended September 30,		
	2019	2018	Increase (Decrease)
Salaries and staff costs	$ 399,962	$ 354,643	$ 45,319
Stock-based compensation	104,153	130,300	(26,147)
Clinical trials, outside services, and lab supplies	2,052,224	1,023,201	1,029,023
Facilities and other	262,485	322,297	(59,812)
Total research and development	$ 2,818,824	$ 1,830,441	$ 988,383

Research and development expenses increased by $988,383 to $2,818,824 for the three months ended September 30, 2019 from $1,830,441 for the same period in 2018. The overall increase in research and development expenses was primarily due to costs associated with clinical programs and outside service costs for two ongoing clinical trials and the start of a third c

linical trial related to the development of our lead drug candidate, onvansertib. We expect an increase in research and development costs as we advance the development of onvansertib.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted of the following:

	Three Months Ended September 30,		
	2019	2018	Increase (Decrease)
Salaries and staff costs	$ 468,821	$ 535,582	$ (66,761)
Stock-based compensation	162,172	147,921	14,251
Outside services and professional fees	507,074	494,208	12,866
Facilities and other	302,272	487,489	(185,217)
Total selling, general and administrative	$ 1,440,339	$ 1,665,200	$ (224,861)

Selling, general and administrative expenses decreased by $224,861 to $1,440,339 for the three months ended September 30, 2019 from $1,665,200 for the same period in 2018. The significant components of the decrease were primarily due to the decrease in facilities and other costs, and salaries and staff costs. The decreased facilities and other cost was due to a decrease in marketing costs for the three months ended September 30, 2019 as compared to the same period of 2018. The decreased salaries and staff cost for the three months ended September 30, 2019 as compared to the same period of 2018, was due to decreased headcount in 2019.

Interest Income

Interest income was $53,700 for the three months ended September 30, 2019 as compared to $85,938 for the same period of 2018. The decrease of interest income is primarily due to a lower money market fund average balance for the three months ended September 30, 2019 as compared to the same period of 2018.

Change in Fair Value of Derivative Financial Instruments — Warrants

We have issued warrants that are accounted for as derivative liabilities. As of September 30, 2019, the derivative financial instruments—warrants liabilities were revalued to $4,956, resulting in a decrease in value of $13,330 from June 30, 2019, based primarily upon the fluctuation in our stock price as well as the changes in the expected term, volatility, and risk-free interest rates for the expected term. The decrease in value upon remeasurement at September 30, 2019 was recorded as a gain from the change in fair value of derivative financial instruments—warrants in the condensed statement of operations.

Net Loss

Net loss and per share amounts were as follows:

	Three Months Ended September 30,		
	2019	2018	Increase (Decrease)
Net loss attributable to common shareholders	$ (4,147,609)	$ (3,775,628)	$ 371,981
Net loss per common share — basic	$ (0.71)	$ (1.10)	$ (0.39)
Net loss per common share — diluted	$ (0.71)	$ (1.10)	$ (0.39)
Weighted average shares outstanding — basic	5,822,818	3,437,100	2,385,718
Weighted average shares outstanding — diluted	5,822,818	3,437,100	2,385,718

The $371,981 increase in net loss attributable to common shareholders was primarily the result of the increase in operating expenses of $0.3 million for three months ended September 30, 2019 compared to the same period in the prior year. The $0.39 decrease in basic net loss per share was impacted by the increase in basic weighted average shares outstanding resulting primarily from the issuance of approximately 1.4 million shares of common stock upon exercise of warrants, sales of approximately 0.9 million shares of common stock through public and direct offerings, and 0.3 million shares of common stock upon conversion of Series C Convertible Preferred Stock.

Nine Months Ended September 30, 2019 and 2018

Revenues

Our total revenues were $152,055 and $300,310 for the nine months ended September 30, 2019 and 2018, respectively. The components of our revenues were as follows:

	Nine Months Ended September 30,		
	2019	2018	Increase (Decrease)
Royalties	$ 150,560	$ 174,046	$ (23,486)
Services and other	1,495	126,264	(124,769)
Total revenues	$ 152,055	$ 300,310	$ (148,255)

The decrease in service and other revenue for the nine months ended September 30, 2019 as compared to the prior period is primarily from the disposition of our CLIA laboratory. We expect our royalties to fluctuate as the royalties are sales-based or usage-based royalties on our intellectual property license. Revenue recognition of the royalty depends on the timing and overall sales activities of the licensees.

Cost of Revenues

Our total cost of revenues was $0 for the nine months ended September 30, 2019, compared to $597,457 in the same period of 2018. Cost of revenues mainly relates to the costs of our diagnostic service revenues. The decrease in cost of revenues for the nine months ended September 30, 2019 compared to the same period of last year is mainly due to the disposition of our CLIA laboratory. We do not expect any cost of revenue based on our current business model.

Research and Development Expenses

Research and development expenses consisted of the following:

	Nine Months Ended September 30,		
	2019	2018	Increase (Decrease)
Salaries and staff costs	$ 1,183,901	$ 1,270,042	$ (86,141)
Stock-based compensation	300,291	637,821	(337,530)
Clinical trials, outside services, and lab supplies	6,115,127	2,988,198	3,126,929
Facilities and other	698,444	770,985	(72,541)
Total research and development	$ 8,297,763	$ 5,667,046	$ 2,630,717

Research and development expenses increased by $2,630,717 to $8,297,763 for the nine months ended September 30, 2019 from $5,667,046 for the same period in 2018. The overall increase in research and development expenses was primarily due to the increased clinical trials and outside service costs for two ongoing clinical trials and the start of a third clinical trial related to the development of our lead drug candidate, onvansertib. We expect an increase in research and development costs as we advance the development of onvansertib.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted of the following:

	Nine Months Ended September 30,		
	2019	2018	Increase (Decrease)
Salaries and staff costs	$ 1,449,979	$ 2,335,228	$ (885,249)
Stock-based compensation	314,935	1,237,343	(922,408)
Outside services and professional fees	1,541,120	1,499,810	41,310
Facilities and other	937,456	1,248,667	(311,211)
Total selling, general and administrative	$ 4,243,490	$ 6,321,048	$ (2,077,558)

Selling, general and administrative expenses decreased by $2,077,558 to $4,243,490 for the nine months ended September 30, 2019 from $6,321,048 for the same period in 2018. The significant components of the decrease were primarily due to the decrease in salaries and staff costs, stock-based compensation, and facilities costs. The decreased salaries and staff cost for the nine months ended September 30, 2019 as compared to the same period of 2018, was due to decreased headcount in 2019, and a one-time executive severance expense occurring in the second quarter of 2018. The decreased stock-based compensation related to a one-time employee stock option grant in lieu of cash bonuses occurring in January 2018, these options were immediately expensed. 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.

Interest Income and Expense

Interest income was $188,204 for the nine months ended September 30, 2019 as compared to $143,911 for the same period of 2018. The increase of interest income is primarily due to a higher money market fund average balance for the nine months ended September 30, 2019 as compared to the same period of 2018. Interest expense was $0 for the nine months ended September 30, 2019 as compared to $25,177 for the same period of 2018. The decrease of interest expense is resulting from pay-off 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 September 30, 2019, the derivative financial instruments—warrants liabilities were revalued to $4,956, resulting in a decrease in value of $27,359 from December 31, 2018, based primarily upon the fluctuation in our stock price as well as the changes in the expected term, volatility, and risk-free interest rates for the expected term. The decrease in value upon remeasurement at September 30, 2019 was recorded as a gain from the change in fair value of derivative financial instruments—warrants in the condensed statement of operations.

Net Loss

Net loss and per share amounts were as follows:

	Nine Months Ended September 30,		
	2019	2018	Increase (Decrease)
Net loss attributable to common shareholders	$ (12,458,072)	$ (15,090,413)	$ (2,632,341)
Net loss per common share — basic	$ (2.46)	$ (8.27)	$ (5.81)
Net loss per common share — diluted	$ (2.46)	$ (8.27)	$ (5.81)
Weighted average shares outstanding — basic	5,056,794	1,824,208	3,232,586
Weighted average shares outstanding — diluted	5,056,794	1,824,208	3,232,586

The $2,632,341 decrease in net loss attributable to common shareholders was primarily the result of a decrease in Series B deemed dividend expense of $2.8 million, and a decrease in operating expenses of $0.7 million, offset by a decrease in gain from change in fair value of derivative financial instruments-warrants of $0.5 million for the nine months ended September 30, 2019 compared to the same period in the prior year. The $5.81 decrease in basic net loss per share was impacted by the

decrease in operating expense and the increase in basic weighted average shares outstanding resulting primarily from the issuance of approximately 1.4 million shares of common stock upon exercise of warrants, sales of approximately 0.9 million shares of common stock through public and direct offerings, and 0.3 million shares of common stock upon conversion of Series C Convertible Preferred Stock.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2019, we had $9,032,206 in cash and cash equivalents. Net cash used in operating activities for the nine months ended September 30, 2019 was $9,990,636, compared to $9,586,233 for the nine months ended September 30, 2018. Our use of cash was primarily a result of the net loss of $12,171,623 for the nine months ended September 30, 2019, adjusted for non-cash items related to stock-based compensation of $615,226, depreciation and amortization of $130,219, release of clinical trial funding commitment of $509,034, and the loss from the change in fair value of derivative financial instruments—warrants of $27,359. The net change in our operating assets and liabilities was $953,867 offsetting cash used in operations. 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 $67,622 during the nine months ended September 30, 2019, compared to $22,842 for the same period in 2018, both of which were for capital expenditures.

Net cash provided in financing activities was $7,637,331 during the nine months ended September 30, 2019, compared to $16,403,540 for the same period in 2018. Net cash provided in financing activities during the nine months ended September 30, 2019 was primarily from $4.4 million from the sale of common stock and warrants, net of expenses and $3.3 million of proceeds from the exercise of warrants. Net cash provided in financing activities during the nine months ended September 30, 2018 was primarily from $11.8 million of proceeds from the sale of common stock and warrants, net of expenses, and $1.6 million from the proceeds from the exercise of warrants, offset by $1.2 million of repayments of equipment line of credit.

As of September 30, 2019, and December 31, 2018, we had working capital of $5,805,970 and $9,799,947, respectively.

On October 30, 2019, we closed a private placement with certain institutional investors for gross proceeds of approximately $5.0 million. We sold an aggregate of 2,756,340 shares of common stock (including common stock equivalents) and Series G and Series H Warrants to purchase 2,756,340 shares of Common Stock for each class of Warrant.

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 into the third quarter of 2020. 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; or (4) Engaging in strategic partnerships. We continually assess our spending plans to effectively and efficiently address our liquidity needs.

CONTRACTUAL OBLIGATIONS

For a discussion of our contractual obligations see (i) our Financial Statements and Notes to Financial Statements Note 10. *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, 2018.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash and cash equivalents primarily consists of deposits and money market deposits managed by commercial banks as of September 30, 2019. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments.

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 as of September 30, 2019. 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 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. We did not incur significant foreign currency gains or losses for the nine months ended September 30, 2019.

Effects of Inflation

We do not believe that inflation and changing prices during the nine months ended September 30, 2019 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 officer (CEO) and principal financial officer (VP, Finance), of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2019 to provide reasonable assurance that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

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

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the three months ended September 30, 2019 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

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, 2018.

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
10.1	Form of Purchase Agreement (incorporated by reference to Exhibit 10.1 filed with Form 8-K on October 28, 2019)
10.2	Form of Series G, H and Pre-Funded Warrant (incorporated by reference to Exhibit 10.2 filed with Form 8-K on October 28, 2019)
10.3	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.3 filed with Form 8-K on October 28, 2019)
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.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

SIGNATURES

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

TROVAGENE, INC.

November 7, 2019 By: /s/ Thomas Adams

Thomas Adams

Chief Executive Officer

TROVAGENE, INC.

November 7, 2019 By: /s/ Brigitte Lindsay

Brigitte Lindsay

VP, Finance

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Thomas Adams, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Trovagene, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 7, 2019

/s/ Thomas Adams

Thomas Adams

Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Brigitte Lindsay, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Trovagene, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 7, 2019

/s/ Brigitte Lindsay

Brigitte Lindsay

VP, Finance

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Trovagene, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas Adams, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 7, 2019

/s/ Thomas Adams

Thomas Adams

Chief Executive Officer

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Trovagene, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brigitte Lindsay, VP, Finance of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 7, 2019

/s/ Brigitte Lindsay

Brigitte Lindsay
VP, Finance