Trovagene, Inc.
Form 10-Q
November 07, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)
x QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018

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)

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	o (Do not check if a smaller reporting company)	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, 2018, the issuer had 22,990,942 shares of Common Stock issued and outstanding.

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TROVAGENE, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TROVAGENE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$15,065,913	$8,225,764
Accounts receivable and unbilled receivable	128,577	77,095
Prepaid expenses and other current assets	849,082	1,165,828
Total current assets	16,043,572	9,468,687
Property and equipment, net	1,627,605	2,426,312
Other assets	249,645	389,942
Total Assets	$17,920,822	$12,284,941
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$476,300	$825,244
Accrued expenses	1,718,060	1,454,587
Deferred rent, current portion	472,251	334,424
Current portion of long-term debt	—	1,331,515
Total current liabilities	2,666,611	3,945,770
Derivative financial instruments—warrants	70,347	649,387
Deferred rent, net of current portion	1,204,109	1,183,677
Total Liabilities	3,941,067	5,778,834
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, 2018 and December 31, 2017 with liquidation preference of $606,000 at September 30, 2018 and December 31, 2017; 8,860 designated as Series B Convertible Preferred Stock; 0 shares outstanding at September 30, 2018 and December 31, 2017, respectively	60	60
Common stock, $0.0001 par value, 150,000,000 shares authorized; 22,957,192 and 4,399,299 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	7,738	5,279
Additional paid-in capital	201,998,634	179,546,954
Accumulated deficit	(188,026,677)	(173,046,186)
Total stockholders' equity	13,979,755	6,506,107
Total liabilities and stockholders' equity	$17,920,822	$12,284,941

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Royalties	$72,568	$58,779	$174,046	$169,415
Diagnostic services	4,303	58,119	83,650	142,482
Clinical research services	11,490	6,431	42,614	8,481
Total revenues	88,361	123,329	300,310	320,378
Costs and expenses:				
Cost of revenues	26,677	473,202	597,457	1,427,831
Research and development	1,830,441	1,414,706	5,667,046	6,676,251
Selling, general and administrative	1,665,200	4,079,514	6,321,048	12,358,290
Restructuring charges (benefit)	421,351	(46,472)	664,686	1,669,526
Total operating expenses	3,943,669	5,920,950	13,250,237	22,131,898
Loss from operations	(3,855,308)	(5,797,621)	(12,949,927)	(21,811,520)
Interest income	85,938	20,650	143,911	132,515
Interest expense	(16)	(37,123)	(25,177)	(1,010,256)
(Loss) gain from change in fair value of derivative financial instruments—warrants	(2,500)	1,528,669	579,040	2,012,747
Gain (loss) on extinguishment of debt	—	—	17,974	(1,655,825)
Other income (loss), net	2,318	(6,541)	(68,521)	(4,975)
Net loss	(3,769,568)	(4,291,966)	(12,302,700)	(22,337,314)
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)	—
Net loss attributable to common stockholders	$(3,775,628)	$(4,298,026)	$(15,090,413)	$(22,355,494)
Net loss per common share — basic	$(0.18)	$(1.41)	$(1.38)	$(8.17)
Net loss per common share — diluted	$(0.18)	$(1.41)	$(1.38)	$(8.17)
Weighted-average shares outstanding — basic	20,622,660	3,038,806	10,945,249	2,735,526
Weighted-average shares outstanding — diluted	20,622,660	3,038,806	10,945,249	2,735,526

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$(3,769,568)	$(4,291,966)	$(12,302,700)	$(22,337,314)
Other comprehensive income (loss):				
Foreign currency translation loss	—	(1,544)	—	(13,486)
Unrealized gain or reversal of previous losses on securities available-for-sale	—	—	—	9,065
Total other comprehensive loss	—	(1,544)	—	(4,421)
Total comprehensive loss	(3,769,568)	(4,293,510)	(12,302,700)	(22,341,735)
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)	—
Comprehensive loss attributable to common stockholders	$(3,775,628)	$(4,299,570)	$(15,090,413)	$(22,359,915)

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, January 1, 2018	60,600	$ 60	4,399,299	$ 5,279	$179,546,954	$(173,046,186)	$6,506,107
Stock-based compensation	—	—	—	—	1,905,652	—	1,905,652
Sale of common stock and warrants, net of expenses	—	—	9,140,000	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	—	—	473,497	569	1,612,098	—	1,612,667
Issuance of common stock upon vesting of restricted stock units	—	—	77,572	90	(90)	—	—
Issuance of common stock upon conversion of Series B Convertible Preferred Stock	(8,860)	(9)	8,860,000	886	(877)	—	—
Preferred stock dividend payable on Series A Convertible Preferred Stock	—	—	—	—	—	(18,180)	(18,180)
Issuance of common stock for share rounding as a result of reverse stock split	—	—	6,824	—	—	—	—
Cumulative adjustment upon adoption of ASC 606	—	—	—	—	—	109,922	109,922
Net loss	—	—	—	—	—	(12,302,700)	(12,302,700)
Balance, September 30, 2018	60,600	$ 60	22,957,192	$ 7,738	$201,998,634	$(188,026,677)	$13,979,755

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net loss	$(12,302,700)	$(22,337,314)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of assets	197,490	28,199
Impairment loss	187,500	485,000
Depreciation and amortization	701,774	956,995
Stock based compensation expense	1,905,652	3,117,364
(Gain) loss on extinguishment of debt	(17,974)	1,655,825
Accretion of final fee premium	—	293,614
Amortization of discount on debt	—	113,780
Net realized loss on short-term investments	—	6,400
Amortization of premiums on short-term investments	—	9,230
Deferred rent	(266,556)	(207,435)
Interest income accrued on short-term investments	—	(90,330)
Change in fair value of derivative financial instruments—warrants	(579,040)	(2,012,747)
Changes in operating assets and liabilities:		
Increase in other assets	(170,602)	—
Decrease (increase) in accounts receivable and unbilled receivable	58,440	(77,667)
Decrease in prepaid expenses and other current assets	316,746	18,230
Increase (decrease) in accounts payable and accrued expenses	383,037	(1,908,796)
Net cash used in operating activities	(9,586,233)	(19,949,652)
Investing activities:		
Proceeds from disposals of capital equipment	27,942	—
Capital expenditures	(5,100)	(136,251)
Maturities of short-term investments	—	16,431,837
Purchases of short-term investments	(31,500)	(8,804,604)
Sales of short-term investments	31,500	16,434,553
Net cash provided by investing activities	22,842	23,925,535
Financing activities:		
Proceeds from sales of common stock and warrants, net of expenses of $1,336,123 and $575,516, respectively	11,779,525	6,634,803
Proceeds from sales of Series B Convertible Preferred Stock, net of expenses of $497,617	4,386,762	—
Proceeds from exercise of warrants	1,612,667	—
Payment upon debt extinguishment	(175,381)	(1,613,067)
Repayments of long-term debt	—	(15,000,000)
Repayments of equipment line of credit	(1,200,033)	(469,578)
Net cash provided by (used in) financing activities	16,403,540	(10,447,842)
Effect of exchange rate changes on cash and cash equivalents	—	(8,837)
Net change in cash and cash equivalents	6,840,149	(6,480,796)

Cash and cash equivalents—Beginning of period	8,225,764	13,915,094
Cash and cash equivalents—End of period	$15,065,913	$7,434,298
Supplementary disclosure of cash flow activity:		
Cash paid for taxes	$800	$800
Cash paid for interest	$22,482	$650,331
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	$—
Common stock issued upon conversion of Series B Convertible Preferred Stock	$886	$—

See accompanying notes to the unaudited condensed consolidated financial statements.

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

1. Organization and Basis of Presentation

Business Organization and Overview

Trovagene, Inc. (“Trovagene” or the “Company”) headquartered in San Diego, California, is a clinical-stage, oncology therapeutics company, taking a precision cancer medicine approach to develop drugs that target mitosis (cell division) to treat various types of cancer, including leukemias, lymphomas and solid tumors.

Trovagene’s intellectual property and proprietary technology enables the Company to analyze circulating tumor DNA (“ctDNA”) and clinically actionable markers. Unique to the Company’s clinical development plan, and a key component of its precision cancer medicine approach, is the integration of predictive clinical biomarkers to identify patients most likely to respond to treatment.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements of Trovagene, which include all accounts of its wholly owned subsidiary, Trovagene, Srl (dissolved in October 2017), have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). All intercompany balances and transactions have been eliminated in consolidation.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with GAAP and the rules and regulations of the Securities and Exchange Commission (“SEC”) related to a quarterly report on Form 10-Q. Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to those rules and regulations. The unaudited interim condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company’s financial position and the results of its operations and cash flows for the periods presented. The unaudited condensed balance sheet at December 31, 2017 has been derived from the audited financial statements at that date but does not include all of the information and disclosures required by GAAP for annual financial statements. The operating results presented in these unaudited interim condensed consolidated financial statements are not necessarily indicative of the results that may be expected for any future periods. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2017 included in the Company’s annual report on Form 10-K filed with the SEC on February 26, 2018.

The Company made a reverse split of its common stock, $0.0001 par value, at a ratio of 1 for 12, effective June 1, 2018. All share and per share information in the unaudited condensed consolidated financial statements and the accompanying notes have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Liquidity

Trovagene's condensed consolidated financial statements as of September 30, 2018 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, including the net proceeds received from the offering of its equity securities in June 2018, management believes the Company's existing resources will be sufficient to fund the Company's planned operations through July 2019. On April 6, 2018, the Company paid off the outstanding Loan and Security Agreement ("Equipment Line of Credit") entered in November 2015 to Silicon Valley Bank ("SVB"). Based on its current business plan and assumptions, the Company expects to continue to incur significant losses and require significant additional capital to further advance its clinical trial programs and support its other operations. The Company has based its cash sufficiency estimates on its current business plan

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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 October 31, 2018, the Company has received approximately $1.6 million upon exercise of 5,681,667 warrants in connection with the December 2017 public offering. The Company continually assesses its spending plans to effectively and efficiently address its liquidity needs.

NASDAQ Notice

On September 5, 2017, the Company received a written notice from the NASDAQ Stock Market LLC ("NASDAQ") that it was not in compliance with NASDAQ Listing Rule 5550(a)(2) for continued listing on the NASDAQ Capital Market, as the minimum bid price of the Company's common stock had been below $1.00 per share for 30 consecutive business days. In accordance with NASDAQ Listing Rule 5810(c)(3)(A), the Company had a period of 180 calendar days, or until March 5, 2018, to regain compliance with the minimum bid price requirement.

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

On September 7, 2018, the Company received a letter from NASDAQ indicating that, based upon the Company's continued non-compliance with the Minimum Bid Price Rule, the Company's common stock would be subject to delisting unless the Company timely requests a hearing before a NASDAQ Hearings Panel (the "Panel"). The Company timely requested a hearing before the Panel on September 14, 2018, which request will stay any further action by NASDAQ at least pending the issuance of a decision following the hearing and the expiration of any additional extension that may be granted by the Panel. The Company is scheduled to attend the hearing before the Panel on November 8, 2018. The Company is considering all of its options to regain compliance; however, there can be no assurance that the Panel will grant the Company's request for continued listing or that the Company will be able to evidence compliance with the continued listing criteria within the period of time that the Panel may grant it to do so.

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2. Summary of Significant Accounting Policies

During the nine months ended September 30, 2018, there have been no changes to the Company's significant accounting policies as described in its Annual Report on Form 10-K for the fiscal year ended December 31, 2017, except as described below.

Revenue Recognition

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

Royalty and License Revenues

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

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

•Minimum royalties are recognized as earned, and royalties are earned based on the licensee's use. The Company estimates and records licensee's sales based on historical usage rate and collectability.

Diagnostic Service Revenues

Revenue for clinical laboratory tests may come from several sources, including commercial third-party payors, such as insurance companies and health maintenance organizations, government payors, such as Medicare and Medicaid in the United States, patient self-pay and, in some cases, from hospitals or referring laboratories who, in turn, might bill third-party payors for testing. This revenue stream does not meet the criteria for contracts with a customer under ASC 606 because it is not probable that the Company will collect substantially all the consideration to which it will be entitled in exchange for the goods and services transferred, nor can it reliably determine the expected transaction price. Therefore, the Company is recognizing diagnostic service revenue on the cash collection basis until such time as it is able to properly estimate collections on third party reimbursements. As a result of disposition of the its Clinical Laboratory Improvement Amendments ("CLIA") - certified laboratory, this revenue stream is declining and overall insignificant to the Company.

Clinical Research Revenue

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

Restructuring

Restructuring costs are included in loss from operations in the consolidated statements of operations. The Company has accounted for these costs in accordance with ASC Topic 420, Exit or Disposal Cost Obligations. One-time termination benefits are recorded at the time they are communicated to the affected employees. In March 2017, the Company announced a restructuring plan which was completed as of December 31, 2017. In May 2018, the Company closed its CLIA laboratory

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operations. Costs associated with winding down the CLIA laboratory were recorded in the restructuring cost in the September 30, 2018 financial statements. See Note 9 to the consolidated financial statements for further information.

Net Loss Per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator: Net loss attributable to common shareholders	$(3,775,628)	$(4,298,026)	$(15,090,413)	$(22,355,494)
Adjustment for gain from change in fair value of derivative financial instruments—warrants	—	—	—	—
Net loss used for diluted loss per share	$(3,775,628)	$(4,298,026)	$(15,090,413)	$(22,355,494)
Denominator for basic and diluted net loss per share:				
Weighted-average shares used to compute basic loss per share	20,622,660	3,038,806	10,945,249	2,735,526
Adjustments to reflect assumed exercise of warrants	—	—	—	—
Weighted-average shares used to compute diluted net loss per share	20,622,660	3,038,806	10,945,249	2,735,526
Net loss per share attributable to common stockholders:				
Basic	$(0.18)	$(1.41)	$(1.38)	$(8.17)
Diluted	$(0.18)	$(1.41)	$(1.38)	$(8.17)

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,	
	2018	2017
Options to purchase Common Stock	500,246	354,753
Warrants to purchase Common Stock	22,189,533	747,709
Restricted Stock Units	214,872	106,442
Series A Convertible Preferred Stock	5,261	5,261
	22,909,912	1,214,165

Recently Adopted Accounting Pronouncement

In June 2018, the FASB issued ASU 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which amends the FASB Accounting Standards Codification in order to simplify the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU 2018-07, most of the guidance on such payments to nonemployees will be aligned with the requirements for

share-based payments granted to employees. The guidance mandates the modified retrospective approach and is effective for annual and interim reporting periods beginning after December 31, 2018, with early adoption permitted. The Company elected to early adopt this ASU 2018-07 as of September 30, 2018 and the adoption did not have an impact on the Company’s consolidated financial statements.

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Recent Accounting Pronouncement Not Yet Adopted

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 new guidance will be effective for the Company starting in the first quarter of fiscal year 2019. The new standards will impact the Company's accounting for its equipment and office leases and the Company is currently evaluating the impact of the new standards on its consolidated financial statements and processes.

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, 2018 and December 31, 2017:

	Fair Value Measurements at September 30, 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)	$14,974,256	$ —	$ —	$14,974,256
Total Assets	$14,974,256	$ —	$ —	$14,974,256
Liabilities:				
Derivative financial instruments—warrants	$—	$ —	$ 70,347	$70,347
Total Liabilities	$—	$ —	$ 70,347	$70,347

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

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

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the nine months ended September 30, 2018:

Description	Balance at December 31, 2017	Realized (gains) or losses	Balance at September 30, 2018
Derivative financial instruments—warrants	$ 649,387	$ (579,040)	$ 70,347

The change in the fair value of the "derivative financial instruments—warrants" is recorded as a gain or loss in the Company's consolidated statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40 and ASC Topic 480-10. At each reporting period, all assets and

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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, 2018	As of December 31, 2017
Furniture and office equipment	$1,072,156	$1,076,709
Leasehold improvements	1,994,514	1,994,514
Laboratory equipment	912,940	1,426,581
	3,979,610	4,497,804
Less—accumulated depreciation and amortization	(2,352,005)	(2,071,492)
Property and equipment, net	$1,627,605	$2,426,312

5. Equipment Line of Credit

In November 2015, the Company entered into a Loan and Security Agreement (“Equipment Line of Credit”) with SVB that provided for cash borrowings for equipment (“Equipment Advances”) of up to $2.0 million, secured by the equipment financed. Under the terms of the agreement, interest is equal to 1.25% above the Prime Rate. Interest only payments were due on borrowings through November 30, 2016, with both interest and principal payments commencing in December 2016. All unpaid principal and interest on each Equipment Advance will be due on November 1, 2019. The Company has an obligation to make a final payment equal to 7% of total amounts borrowed at the loan maturity date. The Company is also subject to certain affirmative and negative covenants under the Equipment Line of Credit.

On June 20, 2017, the Company received a Notice of Event of Default (“Default Letter”) from SVB which stated that Events of Default had occurred and SVB will decide in its sole discretion whether or not to exercise rights and remedies. On April 6, 2018, the Company paid approximately $1,100,000 to SVB. This payment repaid the outstanding Equipment Line of Credit loan in full. The Company recorded $25,161 in interest expense related to the Equipment Line of Credit during the nine months ended September 30, 2018.

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 consolidated statements of operations. The Company estimates the fair value of these warrants using the Black-Scholes option pricing model.

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

	Nine Months Ended September 30,	
	2018	2017
Estimated fair value of Trovagene common stock	0.77-4.20	8.76-15.12
Expected warrant term	0.3-5.1 years	1.3-5.5 years
Risk-free interest rate	1.76-2.92%	1.27-1.95%
Expected volatility	47-131%	86-109%
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.

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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, 2017	Balance of derivative financial instruments—warrants liability	467,584	$649,387
	Change in fair value of derivative financial instruments—warrants during the period recognized as a gain in the condensed consolidated statements of operations	—	(579,040)
September 30, 2018	Balance of derivative financial instruments—warrants liability	467,584	$70,347

7. Stockholders' Equity

Common Stock

During the nine months ended September 30, 2018, the Company issued a total of 18,557,893 shares of Common Stock. The Company received gross proceeds of approximately $18.0 million from the sale of 9,140,000 shares of its common stock, 20,700,000 warrants, and 8,860 shares of Series B Convertible Preferred Stock through an underwritten public offering in June 2018. 473,497 shares were issued upon exercise of warrants for a weighted-average price of $3.41. 77,572 shares were issued upon vesting of restricted stock units ("RSUs") and 8,860,000 shares were issued upon conversion of 8,860 shares of Series B Convertible Preferred Stock. In addition, 6,824 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 follow:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Included in research and development expense	$130,300	$219,480	$637,821	$798,143
Included in cost of revenue	—	15,633	30,488	56,998
Included in selling, general and administrative expense	147,921	1,186,067	1,237,343	2,387,445
Benefit from restructuring	—	—	—	(125,222)
Total stock-based compensation expense	$278,221	$1,421,180	$1,905,652	$3,117,364

The unrecognized compensation cost related to non-vested stock options outstanding at September 30, 2018 and 2017, net of expected forfeitures, was $499,861 and $3,271,046, respectively, which is expected to be recognized over a weighted-average remaining vesting period of 1.3 and 2.2 years, respectively. The weighted-average remaining contractual term of outstanding options as of September 30, 2018 was approximately 7.6 years. The total fair value of stock options vested during the nine months ended September 30, 2018 and 2017 was $1,515,946 and $3,378,243,

respectively.

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

	Nine Months Ended September 30,	
	2018	2017
Risk-free interest rate	2.5 %	1.82 %
Dividend yield	0 %	0 %
Expected volatility	91 %	87 %
Expected term	5.2 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, 2017	374,251	$ 48.52	$ —
Granted	316,744	$ 3.12	
Canceled / Forfeited	(189,540)	$ 36.50	
Expired	(1,209)	$ 36.00	
Balance outstanding, September 30, 2018	500,246	$ 24.35	$ 3,370
Exercisable at September 30, 2018	355,696	$ 30.21	$ 1,950

On May 30, 2018, the number of authorized shares in the Trovagene 2014 Equity Incentive Plan (“2014 EIP”) was increased from 791,667 to 1,458,334. As of September 30, 2018 there were 637,798 shares available for issuance under the 2014 EIP.

Restricted Stock Units

The weighted-average grant date fair value of the RSUs was $0.77 and $19.08 per share during the nine months ended September 30, 2018 and 2017, 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, 2017	106,200	$ 17.22	$391,878
Granted	204,750	$ 0.77	
Vested	(77,572)	$ 13.83	$268,151
Forfeited	(18,506)	$ 24.60	
Non-vested RSUs outstanding, September 30, 2018	214,872	$ 2.14	$175,121

At September 30, 2018 and 2017, total unrecognized compensation cost related to non-vested RSUs were $263,695 and $1,011,494, which are expected to be recognized over a weighted-average period of 2.0 and 2.5 years, respectively. The total fair value of vested RSUs during the nine months ended September 30, 2018 and 2017 were $1,072,714 and $1,285,578, respectively.

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Warrants

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

	Total Warrants (1)	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (1)
Balance outstanding, December 31, 2017	1,936,641	$ 11.34	4.4
Granted	20,700,000	$ 1.10	
Exercised	(447,108)	$ 3.60	
Balance outstanding, September 30, 2018	22,189,533	$ 1.94	4.6

(1) Excluded the pre-funded warrants to purchase 26,389 shares of common stock at a nominal exercise price of $0.12 per share. The pre-funded warrants were exercised in full during the nine months ended September 30, 2018.

Series B Convertible Preferred Stock

On June 12, 2018, the Company closed an underwritten public offering for total gross proceeds of $18.0 million. The total related offering costs were approximately $1.8 million. The securities offered by the Company consisted of (i) 9,140,000 shares of common stock, at an offering price of $1.00 per share, (ii) warrants to purchase an aggregate of 20,700,000 shares of common stock, including the over-allotment option for 2,700,000 option warrants, at an exercise price of $1.10 per share, and (iii) 8,860 shares of Series B Convertible Preferred Stock, with a stated value of $1,000, and convertible into an aggregate of 8,860,000 shares of common stock. The conversion feature of the Series B Convertible Preferred Stock at the time of issuance was determined to be beneficial on commitment date. Because the Series B Convertible Preferred Stock is perpetual with no stated maturity date, and the conversions may occur any time from inception, the Company immediately recorded a one-time, non-cash deemed dividend of $2.8 million related to the beneficial conversion feature arising from the issuance of Series B Convertible Preferred Stock. This one-time, non-cash deemed dividend increased the Company’s net loss attributable to common stockholders and net loss per share.

The holders of Series B Convertible Preferred Stock are entitled to receive dividends on an as-if-converted-to-Common-Stock basis when, as and if such dividends are paid on shares of the Common Stock. Each share of Series B Convertible Preferred Stock shall entitle the holder to vote on an as-if-converted-to-Common-Stock basis (not exceeding the Beneficial Ownership Limitation). Upon any liquidation, dissolution or winding-up of the Company, the holders of Series B Convertible Preferred Stock are entitled to participate on an as-if-converted-to-Common Stock basis (without giving effect to the Beneficial Ownership Limitation) with holders of the Common Stock in any distribution of assets of the Company. Each share of Series B Convertible Preferred Stock is convertible at the option of the holder into that number of shares of Common Stock determined by dividing the stated value of $1,000 per share, by the conversion price of $1.00 per share.

As of September 30, 2018, there were no shares of Series B Convertible Preferred Stock outstanding.

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.

Lease Agreements

The Company leases approximately 26,100 square feet of office and laboratory space at a monthly rental rate of approximately $73,000. The lease will expire on December 31, 2021. The Company currently subleases certain office space and records the rental receipt under the subleases as a reduction of its rent expense.

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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 PLK 1. 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 pay $1.0 million for services provided by Nerviano, such as the costs to manufacture drug product, no later than June 30, 2019. As of September 30, 2018, approximately $368,000 has been paid for services provided. Terms of the agreement also provide for the Company to pay royalties based on certain development and sales milestones.

The Company is a party to various agreements under which it licenses technology on an exclusive basis in the field of human diagnostics 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. Restructuring Charges

In May 2018, the Company closed its CLIA laboratory operations in order to streamline the Company's business model. The loss recognized from disposition of CLIA laboratory was reported as restructuring charges, a component of operating loss, in the condensed consolidated financial statements. During the nine months ended September 30, 2018, the Company recorded total restructuring charges of approximately $664,000 for CLIA laboratory disposal transactions, of which, approximately $187,000 was related to impairment loss on CLIA laboratory license, approximately $52,000 was related to loss on disposal of property and equipment and other non-capital assets, and approximately $425,000 was related to loss on sublease of office and laboratory space.

In March 2017, the Company announced a strategic restructuring plan in connection with the expansion of precision medicine therapeutics to its business. The restructuring plan included a reduction in force and was completed in the last quarter of 2017. Restructuring charges of approximately $1.7 million were incurred and have been included as a component of operating loss for the nine months ended September 30, 2017. Of the total restructuring charges, approximately $1.2 million was related to termination of employees and an approximately $0.5 million charge related to impaired license fees.

10. Subsequent Event

Subsequent to the quarter end, the Company entered into an arrangement with Leucadia Life Sciences ("Leucadia") pursuant to which Leucadia will develop a PCR-based assay for onvansertib for AML. The cost of the services under the arrangement are expected to be up to $575,000. The Company's Interim Chief Executive Officer ("CEO"), Dr. Thomas Adams, is a principal stockholder of Leucadia. In addition, in connection with the arrangement, the Company

may enter into a consulting agreement with Tommy Adams, VP of Operations of Leucadia, who is the son of Dr. Adams.

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

Forward-Looking Statements

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

In addition, our business and financial performance may be affected by the factors that are discussed under "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2017, filed on February 26, 2018. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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

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

Overview

We are a clinical-stage, oncology therapeutics company, taking a precision cancer medicine approach to develop drugs that target mitosis (cell division) to treat various types of cancer, including leukemias, lymphomas and solid tumors.

On March 15, 2017, we announced that we licensed onvansertib (PCM-075), a PLK1 inhibitor, from Nerviano, pursuant to a license agreement with Nerviano dated March 13, 2017. 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 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 are enrolling a Phase 1b/2 open-label clinical trial of onvansertib in combination with standard-of-care chemotherapy in patients with AML. The Phase 1b/2 clinical trial is led by Hematologist Jorge Eduardo Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The

University of Texas MD Anderson Cancer Center and Amer Zeidan, MBBS, MHS, assistant professor of Medicine at Yale School of Medicine, Hematology expert at Yale Cancer Center. Nine clinical trial sites across the U.S. are currently participating in this trial. In addition, the Company is enrolling patients for its Phase 2 open-label clinical trial of onvansertib in combination with abiraterone acetate (Zytiga®) and prednisone in patients with mCRPC. This trial is being led by David Einstein, M.D., at the Genitourinary Oncology Program at BIDMC and Harvard Medical School and, in addition to BIDMC, this trial is being conducted at DFCI and MGH.

Our intellectual property and proprietary technology enables us to analyze ctDNA and clinically actionable markers. Unique to our clinical development plan, and a key component of our precision cancer medicine approach, is the integration of predictive clinical biomarkers to identify patients most likely to respond to treatment.

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Onvansertib is a first-in-class, 3rd generation, oral and highly-selective PLK1 inhibitor with apparent antitumor activity in different pre-clinical 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 (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 only mild- to moderate side effects reported, 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 pre-clinical 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®), 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, NHL, mCRPC, CRC, and TNBC.

We continue to focus on advancing our two active clinical trials with onvansertib. We have achieved a number of key milestones during the nine months ended September 30, 2018 and anticipate achieving the following milestones throughout the remainder of 2018 and early 2019:

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

- Complete Phase 1b dose escalation cohorts and identify the recommended Phase 2 dose (“RP2D”) for the Phase 2 continuation trial (dependent upon the number of dose escalation cohorts required to reach the maximum tolerated dose or RP2D of onvansertib).
- Provide topline preliminary safety and efficacy data on the combination of onvansertib + LDAC and the combination of onvansertib + decitabine in patients treated through the end of 2018.
- Present data from the AML trial at the 60th annual American Society of Hematology (“ASH”) conference in December 2018.
-

Initiate the Phase 2 segment of the AML trial, which will enroll approximately 32 patients for continued evaluation of safety and preliminary efficacy of onvansertib in combination with either LDAC or decitabine (provided the RP2D has been determined in Phase 1b).

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

- Complete enrollment and evaluation of the 3 safety lead-in patients with onvansertib at 24 mg/m^2 in combination with abiraterone acetate (Zytiga®) and prednisone.
- Provide topline preliminary safety and efficacy data of onvansertib in combination with abiraterone acetate (Zytiga®) and prednisone in patients treated.
- Present data from the mCRPC trial at the 2019 Genitourinary Cancers Symposium ("ASCO GU")

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During 2018, we have advanced our business with the following activities:

- Announced New Patent Claim Allowances Affirming Broad Patent Portfolio Coverage of NPM1 Mutations by the United States Patent and Trademark Office.

On October 24, 2018, we announced that the U.S. Patent and Trademark Office ("USPTO") has allowed claims that affirm broad coverage of NPM1 mutation testing; Patent Application 14/750331, entitled "Nucleophosmin Protein ("NPM") Mutants, Corresponding Gene Sequences and Uses Thereof." This patent encompasses broad claims around the assessment of NPM1 mutational status in any cancer type, including AML.

- Announced Exclusive License Agreement with Massachusetts Institute of Technology ("MIT") for Combination Therapy of Anti-Androgens and Polo-like Kinase Inhibitors in Prostate Cancer.

On October 3, 2018, we announced that we have entered into an exclusive patent license agreement with the MIT. Under the agreement, we have exclusive rights to develop combination therapies that include anti-androgen or androgen antagonist and a Polo-like Kinase ("PLK") inhibitor for the treatment of cancer. The exclusive license agreement is part of our strategy to explore the efficacy of onvansertib in combination with anti-androgen drugs in cancers including prostate, breast, pancreatic, lung and gastrointestinal.

- Announced Completion of Dosing Cohort of Patients Treated with Onvansertib in Combination with Decitabine in Ongoing Phase 1b/2 AML Trial.

On September 27, 2018, we announced completion of the second dosing cohort of onvansertib in combination with standard-of-care decitabine, in our Phase1b/2 clinical trial in patients with AML. All three patients in the cohort successfully completed treatment with onvansertib at 18mg/m^2, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with decitabine and the combination was well tolerated. The Safety Review Committee ("SRC") has recommended escalating to the next dose level of onvansertib at 27mg/m^2 (approximately a 50% increase) in combination with decitabine.

- Announced Predictive Clinical Biomarker Approach to Identify AML Patients Most Likely to Respond to Onvansertib.

On September 5, 2018, we announced we have developed a method for predicting response to treatment by measuring the ability of onvansertib to inhibit PLK1 in patients with AML. PLK1 uniquely phosphorylates translational control tumor protein ("TCTP") to form pTCTP and inhibition of this enzymatic activity by onvansertib appears to be predictive of patient response to treatment. In the ongoing Phase1b/2 open label clinical trial in AML, PLK1 inhibition is being assessed 3-hours following administration, at the approximate peak concentration (C_{max}) of onvansertib. In the first six patients treated, the greatest target engagement, or inhibition of PLK1, was observed in the three patients who showed a response to treatment. We have filed a U.S. patent application with the United States Patent and Trademark Office ("USPTO") to protect our method for evaluating responsiveness of a cancer to a PLK1 inhibitor by determining the ability of the PLK1 inhibitor to inhibit phosphorylation of a unique target of PLK1 in cells of the cancer.

- Announced European Commission Grants Orphan Drug Designation to Onvansertib (PCM-075) for Treatment of Acute Myeloid Leukemia in Europe.

On August 29, 2018, we announced that the European Commission ("EC") has endorsed the positive opinion of the Committee for Orphan Medicinal Products ("COMP") and has granted Orphan Drug Designation ("ODD") for onvansertib for the treatment of patients with AML. Orphan drug designation by the EC provides regulatory and financial incentives to us, including reduced fees during the product development phase, direct access to centralized marketing

authorization in the EU, and 10-year market exclusivity following product approval.

- Announced Completion of Second Dosing Cohort of Patients Treated with Onvansertib (PCM-075) in Ongoing Phase 1b/2 AML Trial.

On August 16, 2018, we announced completion of the second dosing cohort of onvansertib, in combination with standard-of-care LDAC, in our Phase1b/2 clinical trial in patients with AML. All three patients in the cohort successfully completed treatment with onvansertib at 18 mg/m^2, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with LDAC and the combination was well tolerated. The SRC has recommended escalating to the next dose level of onvansertib at 27 mg/m^2 (approximately a 50% increase) in combination with

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LDAC. Additionally, two patients in the three-patient cohort of onvansertib at 18 mg/m^2 in combination with decitabine have also successfully completed at least one cycle of treatment and recruitment of the third patient to complete this cohort is in process. Four of the eleven patients treated to-date remain on treatment, three are currently receiving a second cycle of treatment and one patient is scheduled to start a fifth cycle of treatment.

- Received United States Adopted Name ("USAN") Approval for "Onvansertib" as Nonproprietary Name for First-in-Class, 3rd Generation PLK1 Inhibitor Drug Candidate, PCM-075.

On August 15, 2018, we announced that the USAN Council has approved "onvansertib" as the nonproprietary (generic) name for our drug candidate, PCM-075.

- Received Positive Opinion for Orphan Drug Designation in the European Union for Onvansertib (PCM-075), Our Investigational Cancer Drug.

On August 1, 2018, we announced that the European Medicines Agency ("EMA") COMP has adopted a positive opinion recommending onvansertib (PCM-075) for designation as an orphan medicinal product for the treatment of AML. The opinion letter sent to us by the COMP stated that "although satisfactory methods of treatment of the condition have been authorized in the EU, PCM-075 will be of significant benefit to those affected by AML."

- Announced Preliminary Clinical Data from First Dosing Cohort Demonstrating Durable Treatment Effect of Onvansertib (PCM-075) in Combination with Cytarabine or Decitabine in Patients with Relapsed or Refractory AML.

On June 27, 2018, we announced preliminary clinical data from the first dosing cohort showing a treatment effect with onvansertib (PCM-075) in combination with LDAC or decitabine, as measured by decreases in leukemic cells in both peripheral blood and bone marrow in patients in its ongoing Phase 1b/2 trial in relapsed or refractory AML. Both blood and bone marrow samples were obtained from patients with relapsed or refractory AML enrolled in the Phase 1b/2 trial prior to, and at timepoints following administration of onvansertib (PCM-075), in combination with cytarabine or decitabine. Among the 6 patients evaluated, no dose-limiting toxicities were observed that would prohibit further escalation of the onvansertib (PCM-075) dosing. Three patients exhibited substantial reductions in the percentage of both circulating leukemic cells within the blood and leukemic cells within the bone marrow. Two of these three patients continued on treatment in the second cycle and further decreases in circulating leukemic cells in the blood and within the bone marrow were observed. One patient had a decrease in his bone marrow blasts from 96% to 40% at the end of cycle 2 and has continued on treatment in cycle 3.

- Announced the Start of Recruitment and Enrollment for Phase 2 Clinical Trial of Onvansertib (PCM-075) in Combination with Zytiga® in Patients with mCRPC.

On June 21, 2018, we announced we have received Institutional Review Board approval from Dana-Farber/Harvard Cancer Center and our Phase 2 clinical trial of onvansertib (PCM-075) in combination with Zytiga® (abiraterone acetate) and prednisone in mCRPC is officially activated and recruiting patients. The trial is being conducted by BIDMC, DFCI, and MGH. David Einstein, MD, Genitourinary Oncology Program at BIDMC, is the principal investigator for the trial.

- Announced Completion of First Dosing Cohort of Patients Treated with Onvansertib (PCM-075) in Combination with Decitabine in Ongoing Phase 1b/2 AML trial.

On June 15, 2018, we announced completion of the first dose cohort of onvansertib (PCM-075) in combination with decitabine in our Phase 1b/2 clinical trial in patients with AML. Three patients were treated with onvansertib (PCM-075) at 12 mg/m^2, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with

decitabine. The combination of onvansertib (PCM-075) and decitabine was well tolerated in all patients. The independent SRC has recommended escalating to the second dose cohort of three patients at 18 mg/m^2 of onvansertib (PCM-075) (approximately a 50% increase) in combination with decitabine.

- Announced Completion of First Dosing Cohort of Patients in Ongoing Phase 1b/2 AML trial of Onvansertib (PCM-075) in AML.

On May 17, 2018, we announced the completion of the first dose cohort in our Phase 1b/2 clinical trial of onvansertib (PCM-075) in combination with LDAC, in AML. Three patients were treated with onvansertib (PCM-075) at 12 mg/

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m^2, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with LDAC. Patients eligible for Phase 1b have relapsed or refractory disease and may have received as many as three prior regimens for treatment of their AML. The combination of onvansertib (PCM-075) and LDAC was well tolerated in all patients. The independent SRC has recommended escalating to the second dose cohort of three patients at onvansertib (PCM-075) at 18 mg/m^2 (approximately a 50% increase) in combination with LDAC.

- Announced Presentation of Data at American Association for Cancer Research ("AACR") Meeting 2018 on Pharmacodynamic and Tumor Biomarkers During Treatment with Onvansertib (PCM-075) and Low-Dose Cytarabine.

On April 17, 2018, we announced the presentation of pharmacodynamic and biomarker data from the first patient to complete a safety treatment cycle in our Phase 1b/2 clinical trial of onvansertib (PCM-075) in AML at the AACR annual meeting in Chicago, IL. The poster entitled Pharmacodynamic and Tumor Biomarker Analysis of a PLK1 Inhibitor, PCM-075, in a Phase 1b/2 Trial for Acute Myeloid Leukemia presents the methodology developed to track dynamic changes in blood leukemic cells, genomic alterations and PLK1 inhibition in AML patients treated with onvansertib (PCM-075) in combination with LDAC.

- Announced Presentation of data at AACR Meeting 2018 Showing Synergy of Onvansertib (PCM-075) in Combination with FLT3 Inhibitors in AML.

On April 16, 2018, we announced the presentation of data showing that onvansertib (PCM-075) exhibits synergistic activity when combined with FLT3 inhibitors in a human xenograft AML model, at the AACR Annual Meeting in Chicago, IL. The poster entitled Selective Polo-like Kinase 1 (PLK1) Inhibitor PCM-075 is Highly Active Alone and Shows Synergy When Combined with FLT3 Inhibitors in Models of Acute Myeloid Leukemia (AML) presents data demonstrating that onvansertib (PCM-075) in combination with quizartinib (Daiichi-Sankyo) resulted in 97.3% tumor growth inhibition, compared to 77.9% with quizartinib and 80.2% with onvansertib (PCM-075) as monotherapy.

- Announced First Patient Successfully Completes Cycle 1 of Treatment with Onvansertib (PCM-075) in Combination with Low-Dose Cytarabinein AML Trial.

On March 5, 2018, we announced that the initial patient successfully completed the first cycle 1 of treatment in our Phase 1b/2 multicenter trial of onvansertib (PCM-075) in combination with LDAC in patients with AML. The patient tolerated the combination well and correlative analyses of blood samples, taken at specified time points, also indicated activity on leukemic blood cells. A significant decrease in the percentage of blood leukemic cells was observed within 24 hours of administering onvansertib (PCM-075) + LDAC. By day 15, within the treatment cycle, the greatest effect was observed with blood leukemic cells showing a decrease from greater than 40% to less than 5%. Additionally, the same tumor DNA mutations (ASXL1 and SRSF2) were detected in the bone marrow and blood, indicating consistency across samples and validity of the analyses. Both DNA mutations appeared to quantitatively track with the decrease in blood leukemic cells.

- Announced Presentation of Data Showing Synergy of Onvansertib (PCM-075) in Combination with Zytiga® (abiraterone acetate) in Castration-Resistant Prostate Cancer Model at 2018 Genitourinary Cancers Symposium.

On February 9, 2018, we announced that preclinical data demonstrating the synergy of onvansertib (PCM-075), our highly-selective PLK1 Inhibitor, in combination with abiraterone acetate (Zytiga® - Johnson & Johnson), will be featured as a Poster Presentation at the 2018 Genitourinary Cancers Symposium on February 9th, in San Francisco, California. The poster entitled Combination of Selective Polo-like Kinase 1 (PLK1) Inhibitor PCM-075 with Abiraterone in Prostate Cancer and Non-Androgen-Driven Cancer Models showcases data from Dr. Michael Yaffe's lab at the Koch Institute for Integrative Cancer Research at Massachusetts Institute of Technology and will be

presented by Dr. Jesse Patterson. The underlying mechanism of synergy was further examined by performing gene-expression comparison across more than 30 different synergistic and non-synergistic cell lines across multiple tumor types. From this analysis, multiple hypothesis-generating mechanisms were identified, one of which was the retinoic acid pathway, which when activated is predictive of synergy.

Our accumulated deficit through September 30, 2018 is $188,026,677. 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

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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, 2018.

Critical Accounting Policies

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS of our Annual Report on Form 10-K as of and for the year ended December 31, 2017, filed with the SEC on February 26, 2018. There have been no changes to our critical accounting policies other than adoption of ASC 606 and ASU 2018-07 since December 31, 2017.

RESULTS OF OPERATIONS

Three Months Ended September 30, 2018 and 2017

Revenues

Our total revenues were $88,361 and $123,329 for the three months ended September 30, 2018 and 2017, respectively. The components of our revenues were as follows:

	Three Months Ended September 30,		
	2018	2017	Increase (Decrease)
Royalties	$72,568	$58,779	$13,789
Diagnostic services	4,303	58,119	(53,816)
Clinical research services	11,490	6,431	5,059
Total revenues	$88,361	$123,329	$(34,968)

The increase in royalty income related primarily to the adoption of ASU 606. We recognized more revenue based on historical data for three months ended September 30, 2018, whereas in the same period of 2017 revenue was recognized on a cash basis. Revenue from diagnostic services is recognized when payment is received for the test results. The amount of payments received was lower in 2018 as compared to the same period in the prior year as we closed down our CLIA laboratory. Revenue from clinical research services consists of revenue from the sale of urine and blood collection supplies and tests performed under agreements with our clinical research and business development partners. Revenue is recognized when control of supplies and/or test results are transferred to customers (upon delivery). There were more sales of clinical research services for the three months ended September 30, 2018 as compared to the same period of 2017.

We expect our royalties to fluctuate as the royalties are sales-based or usage-based royalties on our intellectual property license. Revenue recognition of the royalty depends on the timing and overall sales activities of the licensees.

In addition, we expect a decrease in our diagnostic service revenue and clinical research revenue as a result of disposition of our CLIA laboratory and as we focus on the development of oncology therapeutics.

Cost of Revenues

Our total cost of revenues was $26,677 for the three months ended September 30, 2018, compared to $473,202 in the same period of 2017. Cost of revenues mainly relates to the costs of our diagnostic service revenues. The costs are recognized at the completion of testing. The decrease in cost of revenues for the three months ended September 30, 2018 compared to the same period of last year is mainly due to the disposition of our CLIA laboratory.

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Research and Development Expenses

Research and development expenses consisted of the following:

	Three Months Ended September 30,		
	2018	2017	Increase (Decrease)
Salaries and staff costs	$354,643	$301,919	$52,724
Stock-based compensation	130,300	219,480	(89,180)
Outside services, consultants and lab supplies	1,023,201	604,140	419,061
Facilities	270,032	254,681	15,351
Travel and scientific conferences	32,242	28,000	4,242
Fees, license and other	20,023	6,486	13,537
Total research and development	$1,830,441	$1,414,706	$415,735

Research and development expenses increased by $415,735 to $1,830,441 for the three months ended September 30, 2018 from $1,414,706 for the same period in 2017. The overall increase in research and development expenses was primarily due to the increased outside service costs for clinical studies 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,		
	2018	2017	Increase (Decrease)
Salaries and staff costs	$535,582	$1,327,743	$(792,161)
Board of Directors' fees	105,233	120,085	(14,852)
Stock-based compensation	147,921	1,186,067	(1,038,146)
Outside services and consultants	158,285	318,378	(160,093)
Legal and accounting fees	230,690	609,149	(378,459)
Facilities and insurance	249,209	342,935	(93,726)
Travel and conferences	164,136	45,256	118,880
Fees, license and other	74,144	129,901	(55,757)
Total selling, general and administrative	$1,665,200	$4,079,514	$(2,414,314)

Selling, general and administrative expenses decreased by $2,414,314 to $1,665,200 for the three months ended September 30, 2018 from $4,079,514 for the same period in 2017. The significant components of the decrease were primarily due to the decrease in salaries and staff costs and stock-based compensation. In August 2017, a total of 62,116 shares of immediately vested restricted stock awards ("RSA") were granted to our former CEO. Per the agreement, the income taxes associated with the RSA were also paid by our Company. Therefore, personnel costs and stock-based compensation expenses were higher for the three months ended September 30, 2017 as compared to the same period of 2018. Also, stock-based compensation, a non-cash expense, will fluctuate based on the timing and amount of options granted, forfeitures and the fair value of the options at the time of grant. 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.

Restructuring

In May 2018, we closed our CLIA laboratory operations in order to streamline our business model. The loss recognized from disposition of CLIA laboratory was reported as restructuring charges in the September 30, 2018 condensed consolidated financial statements. For the three months ended September 30, 2018, we recorded total restructuring charges of approximately$421,000, the majority of which was related to loss on sublease of office and laboratory space.

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In March 2017, we announced a strategic restructuring plan in connection with the expansion of precision medicine therapeutics to our business. The restructuring plan included a reduction in force and was completed in the last quarter of 2017. The $46,472 restructuring benefit for the three months ended September 30, 2017 was primarily due to certain employee termination costs expensed was less than estimated.

Interest Income and Expense

Interest income was $85,938 from the three months ended September 30, 2018 as compared to $20,650 for the same period of 2017. The increase of interest income is primarily due to a higher money market fund balance and higher interest rate. Interest expense was $16 for the three months ended September 30, 2018 as compared to $37,123 for the same period of 2017. The decrease of interest expense is resulting from pay-off of our $15.0 million term loan and 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, 2018, the derivative financial instruments—warrants liabilities were revalued to $70,347, resulting in an increase in value of $2,500 from June 30, 2018, based primarily upon the increase in our stock price as well as the changes in the expected term, volatility, and risk-free interest rates for the expected term. The increase in value upon remeasurement at September 30, 2018 was recorded as a loss from the change in fair value of derivative financial instruments—warrants in the condensed consolidated statement of operations.

Net Loss

Net loss and per share amounts were as follows:

	Three Months Ended September 30,		
	2018	2017	Increase (Decrease)
Net loss attributable to common shareholders	$(3,775,628)	$(4,298,026)	$(522,398)
Net loss per common share — basic	$(0.18)	$(1.41)	$(1.23)
Net loss per common share — diluted	$(0.18)	$(1.41)	$(1.23)
Weighted average shares outstanding — basic	20,622,660	3,038,806	17,583,854
Weighted average shares outstanding — diluted	20,622,660	3,038,806	17,583,854

The $522,398 decrease in net loss attributable to common shareholders and the $1.23 decrease in basic net loss per share was primarily the result of a decrease in operating expenses of $2.0 million for the three months ended September 30, 2018 compared to the same period in the prior year, offset by a gain from change in fair value of derivative financial instruments—warrants of $1.5 million from the same period of 2017. Basic net loss per share in 2018 was also impacted by the increase in basic weighted average shares outstanding resulting primarily from the sales of approximately 10.4 million shares of common stock through public offerings and the issuance of approximately 8.9 million shares of common stock upon conversion of Series B Convertible Preferred Stock.

Nine Months Ended September 30, 2018 and 2017

Revenues

Our total revenues were $300,310 and $320,378 for the nine months ended September 30, 2018 and 2017, respectively. The components of our revenues were as follows:

	Nine Months Ended September 30,		
	2018	2017	Increase (Decrease)
Royalties	$174,046	$169,415	$ 4,631
Diagnostic services	83,650	142,482	(58,832)
Clinical research services	42,614	8,481	34,133
Total revenues	$300,310	$320,378	$ (20,068)

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Revenue from diagnostic services is recognized when payment is received for the test results. The amount of payments received was lower in 2018 as compared to the same period in the prior year as we closed down our CLIA laboratory. Revenue from clinical research services consists of revenue from the sale of urine and blood collection supplies and tests performed under agreements with our clinical research and business development partners. Revenue is recognized when control of supplies and/or test results are transferred to customers (upon delivery). There were more sales of clinical research services for the nine months ended September 30, 2018 as compared to the same period of 2017.

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

Cost of Revenues

Our total cost of revenues was $597,457 for the nine months ended September 30, 2018, compared to $1,427,831 in the same period of 2017. Cost of revenues mainly relates to the costs of our diagnostic service revenues. The costs are recognized at the completion of testing. The decrease in cost of revenues for the nine months ended September 30, 2018 compared to the same period of last year is mainly due to the lower volume of tests processed and the disposition of the CLIA laboratory.

Research and Development Expenses

Research and development expenses consisted of the following:

	Nine Months Ended September 30,		
	2018	2017	Increase (Decrease)
Salaries and staff costs	$1,270,042	$1,468,491	$(198,449)
Stock-based compensation	637,821	798,143	(160,322)
Outside services, consultants and lab supplies	2,988,198	1,456,504	1,531,694
Facilities	644,750	842,196	(197,446)
Travel and scientific conferences	91,670	72,901	18,769
Fees, licenses and other	34,565	2,038,016	(2,003,451)
Total research and development	$5,667,046	$6,676,251	$(1,009,205)

Research and development expenses decreased by $1,009,205 to $5,667,046 for the nine months ended September 30, 2018 from $6,676,251 for the same period in 2017. Our costs have decreased primarily due to the decrease in fees, licenses and other, offset by the increase in outside services, consultants and lab supplies costs. The decrease in fees, license and other was primarily due to the $2.0 million license fee payment in March 2017 to Nerviano for development and commercialization rights to onvansertib. The increase in services, consultants and lab supplies costs was mainly due to the clinical studies related to the development of onvansertib. We expect increase in research and development expenses as we continue the development of our lead drug candidate.

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Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted of the following:

	Nine Months Ended September 30,		
	2018	2017	Increase (Decrease)
Salaries and staff costs	$2,335,228	$3,504,507	$(1,169,279)
Board of Directors' fees	355,177	347,205	7,972
Stock-based compensation	1,237,343	2,387,445	(1,150,102)
Outside services and consultants	625,890	925,808	(299,918)
Legal and accounting fees	518,743	3,395,070	(2,876,327)
Facilities and insurance	780,237	963,265	(183,028)
Travel and conferences	264,634	510,205	(245,571)
Fees, license and other	203,796	324,785	(120,989)
Total selling, general and administrative	$6,321,048	$12,358,290	$(6,037,242)

Selling, general and administrative expenses decreased by $6,037,242 to $6,321,048 for the nine months ended September 30, 2018 from $12,358,290 for the same period in 2017. The overall decrease in selling, general and administrative expenses was primarily due to the decrease in legal fees and the reduction in force. Legal fees decreased primarily as a result of a litigation related loss contingency accrual of $2.1 million during the nine months ended September 30, 2017. As part of our restructuring in 2017, we reduced the number of our selling, general and administrative personnel, bringing down our average headcount to eight from thirteen in the same period of the prior year. In addition, in August 2017, a total of 62,116 shares of immediately vested RSA were granted to our former CEO. Per the agreement, the income taxes associated with the RSA were also paid by our Company. This event further increased the personnel costs and stock-based compensation expenses for the nine months ended September 30, 2017 as compared to the same period of 2018.

Restructuring

In May 2018, we closed our CLIA laboratory operations in order to streamline our business model. The loss recognized from disposition of CLIA laboratory was reported as restructuring charges in the September 30, 2018 condensed consolidated financial statements. For the nine months ended September 30, 2018, we recorded total restructuring charges of $664,000 for CLIA laboratory disposal transactions, of which, approximately $187,000 was related to impairment loss on CLIA laboratory license, approximately $52,000 was related to loss on disposal of property and equipment and other non-capital assets, and approximately $425,000 was related to loss on sublease of office and laboratory space.

In March 2017, we announced a strategic restructuring plan in connection with the addition of precision medicine therapeutics to our business. The restructuring plan included a reduction in force and was completed in the last quarter of 2017. Restructuring charges of approximately $1.7 million were incurred and have been included as a component of operating loss for the nine months ended September 30, 2017. Of the total restructuring charges, approximately $1.2 million was related to termination of employees and an approximately $0.5 million charge related to impaired license fees.

Interest Income and Expense

Interest income was $143,911 for the nine months ended September 30, 2018 as compared to $132,515 for the same period of 2017. The increase of interest income is primarily due to the overall increase of money market fund balance.

Interest expense was $25,177 for the nine months ended September 30, 2018, compared to $1,010,256 for the same period of 2017. The decrease of interest expense is due to pay-off of our $15.0 million term loan and 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, 2018, the derivative financial instruments—warrants liabilities were revalued to $70,347, resulting in a decrease in value of $579,040 from December 31, 2017, based primarily upon the decrease 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 was recorded as a gain from the change in fair value of derivative financial instruments—warrants in the condensed consolidated statement of operations.

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Net Loss

Net loss and per share amounts were as follows:

	Nine Months Ended September 30,		
	2018	2017	Increase (Decrease)
Net loss attributable to common shareholders	$(15,090,413)	$(22,355,494)	$(7,265,081)
Net loss per common share — basic	$(1.38)	$(8.17)	$(6.79)
Net loss per common share — diluted	$(1.38)	$(8.17)	$(6.79)
Weighted average shares outstanding — basic	10,945,249	2,735,526	8,209,723
Weighted average shares outstanding — diluted	10,945,249	2,735,526	8,209,723

The $7,265,081 decrease in net loss attributable to common shareholders and the $6.79 decrease in basic net loss per share was primarily the result of a decrease in operating expenses compared to the same period in the prior year, offset by a one-time, non-cash deemed dividend recognized from beneficial conversion features of Series B Convertible Preferred Stock issuance. Basic net loss per share in 2018 was also impacted by the increase in basic weighted average shares outstanding resulting primarily from the sales of approximately 10.4 million shares of common stock through public offerings and direct registered offering and the issuance of approximately 8.9 million shares of common stock upon conversion of Series B Convertible Preferred Stock.

Non-GAAP Disclosure

Adjusted net loss per common share is not a measure of financial performance under GAAP and should not be construed as substitutes for, or superior to, GAAP net loss per common share as a measure of financial performance. However, management may from time to time use both GAAP financial measures and the disclosed non-GAAP financial measures internally to evaluate and manage our operations and to better understand our business. Further, management believes the addition of non-GAAP financial measures provides meaningful supplementary information to, and facilitates analysis by, investors in evaluating our financial performance, results of operations and trends. Our calculations of adjusted net loss per common share may not be comparable to similarly designated measures reported by other companies, since companies and investors may differ as to what type of events warrant adjustment.

The following table reconciles reported net loss per common share to adjusted net loss per common share::

	Nine Months Ended September 30,		
	2018	2017	Increase (Decrease)
Net loss attributable to common shareholders	$(15,090,413)	$(22,355,494)	$(7,265,081)
Adjustment for preferred stock dividend recognized from beneficial conversion features of Series B Convertible Preferred Stock issuance	2,769,533	—	2,769,533
Total adjusted net loss attributable to common shareholders	$(12,320,880)	$(22,355,494)	$(4,495,548)
Adjusted net loss per common share — basic and diluted	$(1.13)	$(8.17)	$(7.04)
Weighted average shares outstanding — basic and diluted	10,945,249	2,735,526	8,209,723
Adjustment for Series B Convertible Preferred Stock	—	—	—
Total adjusted weighted average shares outstanding — basic and diluted	10,945,249	2,735,526	8,209,723

Series B Convertible Preferred Stock was offered to purchasers of the Class A units (common stock) in the June underwritten public offering if, together with the purchase of Class A units, the purchaser, with its affiliates and certain related parties, would beneficially own more than 4.99% of our outstanding stock immediately following the consummation of the offering. The Series B Convertible Preferred Stock serves solely as an ownership blocker. Each share of Series B Convertible

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Preferred Stock is convertible at the option of the holder into that number of shares of Common Stock determined by dividing the stated value of $1,000 per share, by the conversion price equal to $1.00 per share ($1.00 being the purchase price of each Class A unit). The fair value of the common stock into which the Series B Preferred Stock is convertible exceeded the allocated purchase price fair value of the Series B Convertible Preferred Stock at the date of issuance. As such, we concluded that the Series B Convertible Preferred Stock contained a beneficial conversion feature and a corresponding accounting entry and financial statement disclosure was required. Because our Series B Convertible Preferred Stock is perpetual with no stated maturity date, and the conversions may occur any time from inception, we immediately recognized the beneficial conversion feature as a one-time, non-cash deemed dividend at issuance. There will be no need to account for any subsequent similar one-time, non-cash dividends for Series B Convertible Preferred Stock issued in the June public offering.

If not for the requirement to account for this one-time, non-cash deemed dividend arising from this conversion feature which solely accommodated purchasers allowing them to not own more than 4.99% of the Common Stock, the net loss per common share — basic and diluted would have been reduced by $2,769,533 to $12,320,880, and would result in a net loss per share of $1.13.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2018, we had $15,065,913 in cash and cash equivalents. Net cash used in operating activities for the nine months ended September 30, 2018 was $9,586,233, compared to $19,949,652 for the nine months ended September 30, 2017. Our use of cash was primarily a result of the net loss of $12,302,700 for the nine months ended September 30, 2018, adjusted for non-cash items related to stock-based compensation of $1,905,652, gain on extinguishment of debt of $17,974, impairment loss of $187,500, depreciation and amortization of $701,774, and the gain from the change in fair value of derivative financial instruments—warrants of $579,040. The changes in our operating assets and liabilities consisted of higher accounts payable and accrued expenses, an increase in other asset, and a decrease in accounts receivable and unbilled receivable and prepaid expenses. 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 provided by investing activities was $22,842 during the nine months ended September 30, 2018, compared to $23,925,535 for the same period in 2017. Investing activities during the nine months ended September 30, 2018 consisted primarily of proceeds from disposal of capital equipment of $27,942, while investing activities during the six months ended June 30, 2017 consisted primarily of net sales and maturities of short-term investments of $24,061,786.

Net cash provided in financing activities was $16,403,540 during the nine months ended September 30, 2018, compared to $10,447,842 used in financing activities for the same period in 2017. Financing activities during the nine months ended September 30, 2018 related primarily to sales of Common Stock and Series B Convertible Preferred Stock and proceeds from exercise of warrants, offset by the pay-off of our Equipment Line of Credit. Financing activities during the same period of the prior year consisted primarily of the pay-off of term loan resulting in debt extinguishment offset by the sale of common stock.

As of September 30, 2018, and December 31, 2017, we had working capital of $13,376,961 and $5,522,917, respectively.

Based on our current business plan and assumptions, we expect to continue to incur significant losses and require significant additional capital to further advance our clinical trial programs and support our other operations. Considering our current cash resources, we believe our existing resources will be sufficient to fund our planned operations through July 2019. 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

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rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms. We are evaluating all options to raise additional capital, increase revenue, as well as reduce costs, in an effort to strengthen our liquidity position, which may include the following: (1) Raising capital through public and private equity offerings; (2) Introducing operation and business development initiatives to bring in new revenue streams; (3) Reducing operating costs by identifying internal synergies; (4) Engaging in strategic partnerships. We continually assess our spending plans to effectively and efficiently address our liquidity needs.

NASDAQ Notice

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

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

On September 7, 2018, we received a letter from NASDAQ indicating that, based upon our continued non-compliance with the Minimum Bid Price Rule, our common stock would be subject to delisting unless we timely request a hearing before the Panel. We timely requested a hearing before the Panel on September 14, 2018, which request will stay any further action by NASDAQ at least pending the issuance of a decision following the hearing and the expiration of any additional extension that may be granted by the Panel. We are scheduled to attend the hearing before the Panel on November 8, 2018. We are considering all of our options to regain compliance; however, there can be no assurance that the Panel will grant our request for continued listing or that we will be able to evidence compliance with the continued listing criteria within the period of time that the Panel may grant us to do so.

CONTRACTUAL OBLIGATIONS

For a discussion of our contractual obligations see (i) our Financial Statements and Notes to Consolidated Financial Statements Note 9. Commitments and Contingencies, and (ii) Item 7 Management Discussion and Analysis of Financial Condition and Results of Operations — Contractual Obligations and Commitments, included in our Annual Report on Form 10-K as of December 31, 2017.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash and cash equivalent primary consists of deposits and money market deposits managed by commercial banks as of September 30, 2018. 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. Due to the short-term duration of our investment portfolio and the relatively low risk profile of our investments, a sudden change in interest rates would not have a material effect on the fair market value of our portfolio, nor our operating results or cash flows.

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

Foreign Currency Risk

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

Effects of Inflation

We do not believe that inflation and changing prices during the nine months ended September 30, 2018 had a significant impact on our results of operations.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We have performed an evaluation under the supervision and with the participation of our management, including our principal executive and financial officer, of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”). Based on that evaluation, our principal executive and financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2018 to provide reasonable assurance that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

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

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the three months ended September 30, 2018 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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, 2017 except for the following:

Our Common Stock will be delisted from the Nasdaq Capital Market if the Nasdaq Hearing Panel does not grant our request for continued listing.

On September 7, 2018, we received a letter from NASDAQ indicating that, based upon our continued non-compliance with the Minimum Bid Price Rule, our common stock would be subject to delisting unless we timely request a hearing before the Panel. We timely requested a hearing before the Panel on September 14, 2018. We are scheduled to attend the hearing before the Panel on November 8, 2018. We are considering all of our options to regain compliance; however, there can be no assurance that the Panel will grant our request for continued listing or that we will be able to evidence compliance with the continued listing criteria within the period of time that the Panel may grant us to do so. If our common stock is delisted from NASDAQ, they may trade in the U.S. on the over-the-counter market, which is a less liquid market. In such case, our shareholders' ability to trade, or obtain quotations of the market value of, our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

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
31.1	

	Certification of Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Labels Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase

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SIGNATURES

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

TROVAGENE, INC.

November 7, 2018 By: /s/ Thomas Adams
Thomas Adams
Interim Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)