UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **August 3, 2018**

Trovagene, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35558**	**27-2004382**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	IRS Employer Identification No.)

11055 Flintkote Avenue
San Diego, CA 92121
(Address of principal executive offices)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

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. ☐

Item 2.02 Results of Operations and Financial Condition

On August 3, 2018, Trovagene, Inc. issued a press release announcing company highlights and financial results for the second quarter ended June 30, 2018. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1	Press Release of Trovagene, Inc. dated August 3, 2018

SIGNATURE

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 hereunto duly authorized.

Dated: August 3, 2018

TROVAGENE, INC.

By: /s/ Thomas Adams
Thomas Adams
Interim Chief Executive Officer

Trovagene Announces Second Quarter 2018 Highlights and Financial Results

SAN DIEGO, CA – August 3, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, developing targeted therapeutics for the treatment of leukemias, lymphomas and solid tumor cancers, today announced company highlights and financial results for the second quarter ended June 30, 2018. The company is issuing this press release in lieu of conducting a conference call.

“We are continuing to advance our clinical development of PCM-075 in Acute Myeloid Leukemia (AML) and metastatic Castration-Resistant Prostate Cancer (mCRPC), achieving several key milestones during the second quarter,” said Tom Adams, Executive Chairman of Trovagene. “In our AML trial, we have successfully completed treatment of 10 patients with PCM-075, 6 at the first dose level of 12 mg/m^2 and 4 at the second dose level of 18 mg/m^2, in combination with either low-dose cytarabine (LDAC) or decitabine. I’m also pleased to report that we received Investigational Review Board (IRB) approval for our Phase 2 trial of PCM-075 in combination with abiraterone acetate (Zytiga®) in patients with mCRPC from the Harvard Medical Cancer Centers and patient recruitment is underway.”

During the second quarter of 2018 the Company has advanced its business with the following activities:

- **Announced Preliminary Clinical Data from First Dosing Cohort Demonstrating Durable Treatment Effect of PCM-075 in Combination with Cytarabine or Decitabine in Patients with Relapsed or Refractory AML** On June 27, 2018, Trovagene announced preliminary clinical data from the first dosing cohort showing a treatment effect with PCM-075 in combination with low-dose cytarabine (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 Acute Myeloid Leukemia (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 PCM-075, in combination with cytarabine or decitabine. Among the 6 patients evaluated, no dose-limiting toxicities (DLTs) were observed that would prohibit further escalation of the 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 PCM-075 in Combination with Zytiga® in Patients with mCRPC**
  On June 21, 2018, Trovagene announced it has received Institutional Review Board (IRB) approval from Dana-Farber/Harvard Cancer Center and its Phase 2 clinical trial of PCM-075 in combination with Zytiga® (abiraterone acetate) and prednisone in mCRPC is officially activated and recruiting patients. The trial is being conducted by Beth Israel Deaconess Medical Center (BIDMC), Dana-Farber Cancer Institute (Dana-Farber), and Massachusetts General Hospital Cancer Center (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 PCM-075 in Combination with Decitabine in Ongoing Phase 1b/2 AML trial**
  On June 15, 2018, Trovagene announced completion of the first dose cohort of PCM-075 in combination with decitabine, in its Phase 1b/2 clinical trial in patients with AML. Three patients were treated with 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 PCM-075 and decitabine was well tolerated in all patients. The independent Safety Review Committee (SRC) has recommended escalating to the second dose cohort of three patients at 18 mg/m^2 of 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 PCM-075 in Acute Myeloid Leukemia**
  On May 17, 2018, Trovagene announced the completion of the first dose cohort in its Phase 1b/2 clinical trial of PCM-075 in combination with LDAC, in AML. Three patients were treated with PCM-075 at 12 mg/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 PCM-075 and LDAC was well tolerated in all patients. The independent Safety Review Committee (SRC) has recommended escalating to the second dose cohort of three patients at PCM-075 at 18 mg/m^2 (approximately a 50% increase) in combination with LDAC.

- **Announced Presentation of Data at AACR Meeting 2018 on Pharmacodynamic and Tumor Biomarkers During Treatment with PCM-075 and Low-Dose Cytarabine**
  On April 17, 2018, Trovagene announced the presentation of pharmacodynamic and biomarker data from the first patient to complete a safety treatment cycle in its Phase 1b/2 clinical trial of PCM-075 in AML at the American Association for Cancer Research (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 PCM-075 in combination with LDAC.

- **Announced Presentation of data at AACR Meeting 2018 Showing Synergy of PCM-075 in Combination with FLT3 Inhibitors in Acute Myeloid Leukemia (AML)**
  On April 16, 2018, Trovagene announced the presentation of data showing that 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 PCM-075 in combination with quizartinib (Daiichi-Sankyo) resulted in 97.3% tumor growth inhibition (TGI), compared to 77.9% with quizartinib and 80.2% with PCM-075 as monotherapy.

Second Quarter 2018 Financial Results

- Trovagene received gross proceeds of approximately $18.0 million from the sale of 9,140,000 shares of its common stock, 20,700,000 shares of warrants, and 8,600 shares of Series B Convertible Preferred Stock through an underwritten public offering that closed on June 12, 2018.

- Trovagene reported a net loss of $3.7 million and a net loss of $6.5 million attributable to common shareholders, or $0.88 per diluted share in the second quarter of 2018, as compared to a net loss of $8.0 million and a net loss of $8.1 million attributable to common shareholders, or $3.12 per diluted share for the same quarter of 2017. The Company recorded a $2.8 million one-time, non-cash deemed dividend related to the beneficial conversion feature arising from the issuance of Series B Convertible Preferred Stock. Adjusted net loss per common share (non-GAAP) was $0.44 in the second quarter of 2018, as compared to adjusted net loss per common share (non-GAAP) of $3.12 for the same quarter of 2017. There will be no need to account for any subsequent, similar one-time, non-cash deemed dividends for Series B Convertible Preferred Stock issued in the June public offering.

- Total operating expenses were approximately $4.6 million for the three months ended June 30, 2018, a reduction of $1.4 million from $6.0 million for the same period in 2017. The decrease in cash used in operating activities is attributed to having completed the transition from diagnostics to therapeutics and primary focus on advancing development of PCM-075.

- Net cash used in operating activities in the second quarter of 2018 was $3.3 million, compared to $4.6 million in the second quarter of 2017. The year-over-year reduction of $1.3 million can be attributed primarily to the elimination of expenses associated with diagnostic programs and focus on therapeutics and the clinical development of its lead drug candidate, PCM-075.

- Net cash provided by financing activities in the second quarter of 2018 was $15.1 million as compared to $16.7 million used in financing activities in the same period of 2017. Financing activities during the three months ended June 30, 2018 related primarily to the proceeds from sales of common stock and warrants.

- Research and development expenses increased by approximately $1.0 million to $2.0 million for the three months ended June 30, 2018 from $1.0 million 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 drug candidate, PCM-075. We expect increases in research and development costs as we continue to advance the development of PCM-075.

- Selling, general and administrative expenses decreased by approximately $2.5 million to $2.2 million for the three months ended June 30, 2018 from $4.7 million for the same period in 2017. The significant components of the decrease were primarily due to the decrease in legal fees of approximately $2.1 million related to former CEO and CFO litigation settlement.

- The weighted average diluted shares of common stock outstanding used to calculate per share results for the three months ended June 30, 2018 was 7.4 million.

- As of June 30, 2018, Trovagene had approximately $18.5 million of cash and cash equivalents.

About Trovagene, Inc.

Trovagene is a clinical-stage, oncology therapeutics company, using a precision medicine approach to develop drugs that target mitosis (cell division) to treat various types of cancer, including leukemias/lymphomas and solid tumors. Trovagene has intellectual property and proprietary technology that enables the Company to analyze circulating tumor DNA (ctDNA) and clinically actionable markers to identify patients most likely to respond to specific cancer therapies. Trovagene plans to continue to vertically integrate its tumor genomics technology with the development of targeted cancer therapeutics. For more information, please visit https://www.trovagene.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of words such as “anticipate,” “believe,” “forecast,” “estimated” and “intend” or other similar terms or expressions that concern Trovagene’s expectations, strategy, plans or intentions. These forward-looking statements are based on Trovagene’s current expectations and actual

results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, our need for additional financing; our ability to continue as a going concern; clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidates; uncertainties of government or third party payer reimbursement; dependence on key personnel; limited experience in marketing and sales; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; our ability to develop tests, kits and systems and the success of those products; regulatory, financial and business risks related to our international expansion and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. There are no guarantees that any of our technology or products will be utilized or prove to be commercially successful, or that Trovagene's strategy to design its liquid biopsy tests to report on clinically actionable cancer genes will ultimately be successful or result in better reimbursement outcomes. Additionally, there are no guarantees that future clinical trials will be completed or successful or that any precision medicine therapeutics will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in Trovagene's Form 10-K for the year ended December 31, 2017, and other periodic reports filed with the Securities and Exchange Commission. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Trovagene does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

Trovagene Contact:

Vicki Kelemen
VP, Corporate Communications
858-952-7652
vkelemen@trovagene.com

Trovagene, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except for per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Royalties	$ 53	$ 45	$ 102	$ 111
Diagnostic services	39	55	79	84
Clinical research services	20	2	31	2
Total revenues	112	102	212	197
Costs and expenses:				
Cost of revenues	204	338	570	954
Research and development	1,953	982	3,837	5,262
Selling, general and administrative	2,151	4,674	4,656	8,279
Restructuring charges (benefit)	243	(4)	243	1,716
Total operating expenses	4,551	5,990	9,306	16,211
Loss from operations	(4,439)	(5,888)	(9,094)	(16,014)
Net interest income (expense)	35	(432)	33	(861)
Gain (loss) on change in fair value of derivative financial instruments- warrants	711	(72)	581	484
Gain (loss) on extinguishment of debt	18	(1,656)	18	(1,656)
Other (loss) income, net	(72)	2	(71)	2
Net loss	(3,747)	(8,046)	(8,533)	(18,045)
Preferred stock dividend	(2,776)	(6)	(2,782)	(12)
Net loss attributable to common stockholders	$ (6,523)	$ (8,052)	$ (11,315)	$ (18,057)
Net loss per common share – basic and diluted	$ (0.88)	$ (3.12)	$ (1.88)	$ (7.00)
Weighted average shares outstanding – basic and diluted	7,423	2,583	6,026	2,581

Trovagene, Inc.

Condensed Consolidated Balance Sheets

(in thousands)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 18,517	$ 8,226
Accounts receivable and unbilled receivable	124	77
Prepaid expense and other assets	1,002	1,166
Total current assets	19,643	9,469
Property and equipment, net	1,804	2,426
Other assets	321	390
Total Assets	$ 21,768	$ 12,285
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 565	$ 825
Accrued expenses	2,303	1,455
Deferred rent	350	334
Current portion of long-term debt	-	1,332
Total current liabilities	3,218	3,946
Derivative financial instruments - warrants	68	649
Deferred rent, net of current portion	1,005	1,184
Total Liabilities	4,291	5,779
Stockholders' equity	17,477	6,506
Total liabilities and stockholders' equity	$ 21,768	$ 12,285

Trovagene, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

	Six Months Ended June 30,	
	2018	**2017**
Operating activities		
Net loss	$ (8,533)	$ (18,045)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	484	646
Stock based compensation expense	1,627	1,696
Change in fair value of derivative financial instruments - warrants	(582)	(484)
Gain (loss) on extinguishment of debt	(18)	1,656
Other non-cash items	222	709
Changes in operating assets and liabilities	693	467
Net cash used in operating activities	(6,107)	(13,355)
Investing activities:		
Capital expenditures, net	(5)	(21)
Net (purchase) sales and maturities of short-term investments	(32)	24,062
Net cash (used in) provided by investing activities	(37)	24,041
Financing activities:		
Proceeds from sales of common stock and warrants, net of expenses	11,779	107
Proceeds from sales of Series B Convertible Preferred Stock, net of expenses	4,387	-
Proceeds from exercise of warrants	1,613	-
Net repayment of debt	(1,375)	(16,926)
Net cash provided by (used in) financing activities	16,404	(16,819)
Effect of exchange rate changes on cash and cash equivalents	-	(2)
Net change in cash and equivalents	(10,260)	(6,131)
Cash and cash equivalents—Beginning of period	8,226	13,915
Cash and cash equivalents—End of period	$ 18,486	$ 7,784

Trovagene, Inc.

Non-GAAP Financial Measures

Adjusted net loss per common share is not a measure of financial performance under accounting principles generally accepted in the United States ("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 the Company's operations and to better understand its business. Further, management believes the addition of non-GAAP financial measures provides meaningful supplementary information to, and facilitates analysis by, investors in evaluating the Company's financial performance, results of operations and trends. The Company's 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:

	Three Months Ended June 30,	
	2018	**2017**
GAAP net loss per share attributable to stockholders - diluted	$ (0.88)	$ (3.12)
Adjustment for preferred stock dividend recognized from beneficial conversion features of Series B Convertible Preferred Stock issuance	0.44	—
Non-GAAP net loss per share attributable to stockholders - diluted	$ (0.44)	$ (3.12)
GAAP net loss attributable to stockholders	$(6,522,548)	$(8,051,871)
Adjustment for preferred stock dividend recognized from beneficial conversion features of Series B Convertible Preferred Stock issuance	2,769,533	—
Non-GAAP net loss attributable to stockholders	$ (3,753,015)	$ (8,051,871)
GAAP weighted average shares outstanding - diluted	6,026,345	2,581,372
Adjustment for Series B Convertible Preferred Stock	593,094	—
Non-GAAP weighted average shares outstanding - diluted	6,619,439	2,581,372