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): **May 7, 2019**

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:

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

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

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

o 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 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

Securities registered pursuant to Section 12(b) of the Act:

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

Item 2.02 Results of Operations and Financial Condition

On May 7, 2019, Trovagene, Inc. issued a press release announcing company highlights and financial results for the first quarter ended March 31, 2019. 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 May 7, 2019

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: May 7, 2019

TROVAGENE, INC.

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

Trovagene Announces First Quarter 2019 Results and Highlights

SAN DIEGO, CA — May 7, 2019 — Trovagene, Inc. (Nasdaq: TROV), a clinical-stage oncology therapeutics company, using a precision medicine approach to develop drugs that target cell division (mitosis) for the treatment of leukemias, lymphomas and solid tumor cancers, today announced company highlights and financial results for the first quarter ended March 31, 2019. The company is issuing this press release in lieu of conducting a conference call.

"We are pleased with our accomplishments year-to-date, and our onvansertib clinical development programs continue to advance as planned," said Dr. Thomas Adams, Chief Executive Officer and Chairman of Trovagene. "We began the year with presentation of data from our Phase 2 trial in metastatic Castration-Resistant Prostate Cancer (mCRPC) at the Genitourinary Cancers Symposium (ASCO-GU) and followed this with a presentation at the American Association for Cancer Research (AACR) demonstrating activity of onvansertib in prostate cancer patients showing initial resistance to anti-androgen therapy. We also achieved a critical milestone in our ongoing Phase 1b/2 trial in Acute Myeloid Leukemia (AML), with a complete response (2 CR's and 1 CRi) to treatment achieved in 3 of 6 (50%) of evaluable patients at the highest doses of onvansertib (27mg/m^2 and 40mg/m^2) evaluated in combination with standard-of-care chemotherapy, decitabine."

Dr. Adams added, "We achieved a number of key milestones in the first quarter of 2019, including: Successful completion of the first four dose levels, without any dose-limiting toxicities, in the Phase 1b segment of our AML trial; receipt of a "Study May Proceed" notification from the FDA for our Phase 1b/2 trial in metastatic Colorectal Cancer (mCRC) in January and subsequent agreement with PoC Capital to fund this trial."

The Company has advanced its business to-date in 2019, with the following activities and milestone achievements:

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

On April 23, 2019, Trovagene announced preclinical data that provides support for clinical evaluation of onvansertib in combination with venetoclax (Venclexta® - AbbVie) in patients with difficult-to-treat relapsed or refractory acute myeloid leukemia (AML). Preclinical data showed that the combination demonstrated synergy (the combined effect of the two drugs is greater than the sum of their individual effects) with a significant decrease in tumor cell viability.

- **Announced Update to Phase 1b/2 AML Trial Data Presented at AACR - Additional Patients Achieve Complete Response at Two Highest Dose Levels of Onvansertib**

On April 5, 2019, Trovagene announced updates to the Phase1b/2 AML trial data presented at the AACR conference on April 1, 2019. Complete response (2 CR's and 1 CRi) to treatment with onvansertib in combination with decitabine was achieved in 3 of 6 (50%) of evaluable patients at the highest doses (27mg/m^2 and 40mg/m^2). The first complete response was achieved at the highest dose of onvansertib (40mg/m^2) in combination with low-dose cytarabine (LDAC).

Overall, approximately 90% clinical benefit has been achieved to-date in the trial and there have been no dose limiting toxicities observed. Dose escalation is continuing with enrollment in the onvansertib 60mg/m^2 cohort.

· **Announced Early Data from Phase 2 Trial Indicates Activity of Onvansertib in Prostate Cancer Patients Showing Initial Resistance to Anti-Androgen Therapy**

On April 2, 2019, Trovagene announced early data from its ongoing Phase 2 study evaluating onvansertib in combination with Zytiga® in patients with mCRPC. Early prostate specific antigen ("PSA") response was observed when onvansertib is added to abiraterone (Zytiga®) in 2 of 6 patients to-date; the first patient achieved the primary efficacy endpoint of disease stabilization. The PSA trajectory in the patient achieving the primary efficacy endpoint indicates alteration of the natural history of early signs of resistance to Zytiga®. Patients with observed responses to-date harbor the highly aggressive androgen receptor variant (AR-V7) which is known to be resistant to treatment with Zytiga®.

· **Announced Phase 1b/2 Dose Escalation Trial of Onvansertib in Relapsed/Refractory AML Demonstrates Safety, Tolerability and Relative Durability with Complete Responses at Highest Dose Levels**

On April 1, 2019, Trovagene announced the presentation of new data from its ongoing Phase 1b/2 study evaluating onvansertib in combination with standard-of-care chemotherapy in AML. The greatest anti-leukemic activity has been observed in the onvansertib + decitabine arm, with complete response in 2 (1 CR and 1 CRi) of 4 (50%) of evaluable patients from the two highest dose levels. There have been no dose-limiting toxicities observed to-date and two-thirds of patients have completed $\geq$2 cycles of treatment, with 2 patients currently on treatment for more than 11 and 5 months, respectively. There has been a significant association observed between biomarker-positive patients and response to onvansertib treatment.

· **Announced Presentation Update on Phase 2 Study of Onvansertib in Combination with Zytiga® in Patients with mCRPC at ASCO-GU**

On February 14, 2019, Trovagene announced the presentation of a poster reviewing its ongoing Phase 2 study evaluating onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC) at the Genitourinary Cancers Symposium (ASCO-GU) in San Francisco, CA. The data featured demonstrates the safety and tolerability of onvansertib in combination with Zytiga® which was confirmed in the safety lead-in portion of the trial that was completed prior to opening the trial to full enrollment. In addition, a second arm is planned with the goal of maximizing clinical activity by reducing the dosing schedule from the current 21-day cycle to a 14-day cycle.

· **Announced that Trovagene and PoC Capital Entered into an Agreement to Fund Clinical Development of Onvansertib in Metastatic Colorectal Cancer (mCRC)**

On January 29, 2019, Trovagene announced an agreement with PoC Capital to fund its Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin in patients with mCRC with a KRAS mutation. Trovagene submitted an Investigational New Drug (IND) application and protocol to the FDA on December 19, 2018, and received a "study may proceed" notification

from the FDA, 28-days later, on January 16, 2019. The trial is being conducted at two prestigious cancer centers in the U.S.; USC Norris Comprehensive Cancer Center and The Mayo Clinic.

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

On January 23, 2019, Trovagene announced the issuance of a new patent (10,155,006), entitled *Combination Therapies and Methods of Use Thereof for Treating Cancer*, by the U.S. Patent and Trademark Office (USPTO). This patent broadens previously issued patent (9,566,280), by expanding the use of onvansertib to encompass combination therapies with any anti-androgen and androgen antagonist drug, such as Zytiga®, Xtandi® and Erleada® for the treatment of metastatic and non-metastatic castrate-resistant prostate cancer. The issuance of this patent further strengthens Trovagene's existing intellectual property portfolio obtained with the licensing of exclusive global development and commercialization rights to onvansertib from Nerviano Medical Sciences in March, 2017.

First Quarter 2019 Financial Results

Total operating expenses were approximately $4.1 million for the three months ended March 31, 2019, a decrease of $0.7 million from $4.8 million for the same period in 2018. The decrease in operating expenses is attributed to a reduction of $1.0 million in SG&A and $0.4 million for cost of revenues related to the disposition of the CLIA lab, and partially offset by an increase of $0.8 million in R&D costs.

Net cash used in operating activities in the first quarter of 2019 was approximately $3.4 million, compared to $2.9 million in the same period in 2018. The year-over-year increase of $0.5 million can be attributed primarily to funding used to advance the onvansertib clinical trials.

Research and development expenses increased by approximately $0.8 million to $2.6 million for the three months ended March 31, 2019 from $1.9 million for the same period in 2018. 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, onvansertib. We expect increases in research and development costs as we advance the onvansertib clinical development programs in AML, mCRPC and mCRC.

Selling, general and administrative expenses decreased by approximately $1.0 million to $1.5 million for the three months ended March 31, 2019 from $2.5 million for the same period in 2018. The significant components of the decrease were primarily due to the reduction in salaries and staff costs and stock-based compensation.

The weighted average diluted shares of common stock outstanding used to calculate per share results for the three months ended March 31, 2019 was 4.1 million.

As of March 31, 2019, Trovagene had approximately $11.3 million of cash and cash equivalents.

About Trovagene, Inc.

Trovagene is a clinical-stage, oncology therapeutics company, taking 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.trovageneoncology.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. 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, 2018, 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, Clinical Development and Investor Relations
858-952-7652
vkelemen@trovagene.com

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

	Three Months Ended March 31,	
	2019	**2018**
Revenues:		
Royalties	$ 62	$ 49
Services and other	100	51
Total revenues	162	100
Costs and expenses:		
Cost of revenues	—	366
Research and development	2,649	1,884
Selling, general and administrative	1,475	2,505
Total operating expenses	4,124	4,755
Loss from operations	(3,962)	(4,655)
Net interest (income) expense	67	(2)
Loss from change in fair value of derivative financial instruments- warrants	(10)	(130)
Other income	—	1
Net loss	(3,905)	(4,786)
Preferred stock dividend	(274)	(6)
Net loss attributable to common stockholders	$ (4,179)	$ (4,792)
Net loss per common share - basic	$ (1.02)	$ (6.23)
Net loss per common share - diluted	$ (1.02)	$ (6.23)
Weighted average shares outstanding - basic	4,087	769
Weighted average shares outstanding - diluted	4,087	769

Trovagene, Inc.
Condensed Balance Sheets
(in thousands)
(Unaudited)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 11,330	$ 11,453
Accounts receivable and unbilled receivable	116	168
Prepaid expenses	891	1,144
Total current assets	12,337	12,765
Property and equipment, net	293	1,304
Operating lease right-of-use assets	1,816	—
Other assets	87	103
Total Assets	$ 14,533	$ 14,172
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 467	$ 665
Accrued expenses	2,022	1,814
Operating lease liabilities	796	—
Deferred rent	—	486
Total current liabilities	3,285	2,965
Derivative financial instruments - warrants	42	32
Operating lease liabilities, net of current portion	1,520	—
Deferred rent, net of current portion	—	1,091
Total Liabilities	4,847	4,088
Stockholders' equity	9,686	10,084
Total Liabilities and Stockholders' Equity	$ 14,533	$ 14,172

Trovagene, Inc.
Condensed Statements of Cash Flows
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Operating activities		
Net loss	$ (3,905)	$ (4,876)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	46	252
Stock based compensation expense	200	1,406
Change in fair value of derivative financial instruments - warrants	10	130
Other non-cash items	71	(79)
Changes in operating assets and liabilities	218	221
Net cash used in operating activities	(3,360)	(2,856)
Investing activities:		
Capital expenditures, net	(5)	(5)
Net cash used in investing activities	(5)	(5)
Financing activities:		
Costs related to the clinical trial funding commitment	(40)	—
Proceeds from exercise of warrants	3,282	1,449
Repayment of debt	—	(157)
Net cash provided by financing activities	3,242	1,292
Net change in cash and equivalents	(123)	(1,569)
Cash and cash equivalents—Beginning of period	11,453	8,226
Cash and cash equivalents—End of period	$ 11,330	$ 6,657