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): **October 22, 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)

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	Nasdaq Capital Market

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

Item 8.01 Other Events.

On October 22, 2019, Trovagene, Inc. issued a press release announcing data demonstrating positive response to treatment in patients enrolled in its Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for second-line treatment of KRAS-mutated metastatic colorectal cancer (mCRC). A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 Press Release of Trovagene, Inc. dated October 22, 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: October 22, 2019

TROVAGENE, INC.

By: /s/ Thomas Adams

Thomas Adams

Chief Executive Officer

Trovagene Announces Positive Response to Treatment in Phase 1b/2 Trial of Onvansertib in Patients with KRAS-Mutated Metastatic Colorectal Cancer

- ***Highly aggressive KRAS-mutated tumors account for ~50% of metastatic colorectal cancer (mCRC); no targeted treatments available and response to standard-of-care is only 5%***
- ***Decreases in tumor KRAS mutational burden in response to treatment with onvansertib in combination with FOLFIRI/Avastin® observed in all patients with a confirmed KRAS mutation***
- ***KRAS, the trial biomarker, is a well-established measurement for the assessment of tumor mutational burden and prediction of patient response in mCRC***

SAN DIEGO (October 22, 2019) – Trovagene, Inc. (Nasdaq: TROV), a clinical-stage, Precision Cancer Medicine™ oncology therapeutics company developing drugs that target cell division (mitosis) for the treatment of various cancers including prostate, colorectal and leukemia, today announced data demonstrating positive response to treatment in patients enrolled in its Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for second-line treatment of KRAS-mutated metastatic colorectal cancer (mCRC). Decreases in tumor KRAS mutational burden in response to treatment was observed in all four patients who completed their first cycle of therapy with the combination regimen, as measured by quantitative analysis of circulating tumor DNA (ctDNA).

Colorectal cancer (CRC) is the second leading cause of cancer mortality in the U.S. Despite significant progress in the treatment of mCRC, the majority of patients succumb to the disease. Therefore, improving the effectiveness of treatments is critical to changing the outcomes for this patient population. Approximately 50% of mCRC patients have the KRAS mutation. The efficacy of current second-line therapy in terms of survival prolongation and response remains very limited, especially in this population, where there is only a 5% response rate.

“We are pleased by the early indication of response to treatment with the addition of onvansertib to standard-of care in patients with KRAS-mutated mCRC,” said Dr. Thomas Adams, Chief Executive Officer and Chairman of Trovagene. “We believe the combination of onvansertib and FOLFIRI/bevacizumab has the potential to provide a much-needed safe and effective new treatment option for the approximately 50% of patients with KRAS-mutated mCRC.”

“Although still early in the trial, we are encouraged by the decreases in KRAS, assessed following initial dosing with onvansertib in combination with FOLFIRI/ bevacizumab, in patients treated in the first cohort,” said lead investigator Dr. Afsaneh Barzi, associate professor of clinical medicine at Keck School of Medicine of USC and medical oncologist at USC Norris Comprehensive Cancer Center. “Additionally, these patients have continued on treatment beyond the cycle 1 safety assessment, indicating that the regimen appears to be safe and well tolerated. These initial findings suggest that onvansertib may provide clinical benefit for mCRC patients who have limited therapeutic options and a poor prognosis.”

An overview of the mCRC Phase 1b/2 clinical trial (NCT03829410) was also featured in a poster presentation at the European Society for Medical Oncology (ESMO) Annual Congress in September 2019. The presentation included the supportive preclinical data, demonstrating synergy with the combination of onvansertib and irinotecan, a key component of the FOLFIRI regimen.

About the Phase 1b/2 Clinical Trial of Onvansertib in mCRC

The trial, *A Phase 1b/2 Study of Onvansertib (PCM-075) in Combination with FOLFIRI and Bevacizumab for Second-Line Treatment of Metastatic Colorectal Cancer in Patients with a KRAS Mutation* (NCT03829410), will evaluate the safety and efficacy of onvansertib in combination with standard-of-care FOLFIRI and Avastin® (bevacizumab). Up to 44 patients, with a confirmed KRAS mutation, metastatic and unresectable disease, who have failed or are intolerant of treatment with FOLFOX (fluoropyrimidine and oxaliplatin) with or without Avastin® (bevacizumab), will be enrolled. The trial is being conducted at two prestigious cancer centers: USC Norris Comprehensive Cancer Center and The Mayo Clinic Arizona.

About Onvansertib

Onvansertib is a first-in-class, third-generation, oral and highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK1) enzyme, which is over-expressed in multiple cancers including leukemias, lymphomas and solid tumors. Onvansertib targets the PLK1 isoform only (not PLK2 or PLK3), is orally administered and has a 24-hour half-life with only mild-to-moderate side effects reported. Trovagene believes that targeting only PLK1 and having a favorable safety and tolerability profile, along with an improved dose/scheduling regimen will significantly improve on the outcome observed in previous studies with a former panPLK inhibitor in AML.

Onvansertib has demonstrated synergy in preclinical studies with numerous chemotherapies and targeted therapeutics used to treat leukemias, lymphomas and solid tumor cancers, including irinotecan, FLT3 and HDAC inhibitors, taxanes and cytotoxins. Trovagene believes the combination of onvansertib with other compounds has the potential to improve clinical efficacy in acute myeloid leukemia (AML), metastatic castration-resistant prostate cancer (mCRPC), non-Hodgkin lymphoma (NHL), colorectal cancer and triple-negative breast cancer (TNBC), as well as other types of cancer.

Trovagene has three ongoing clinical trials of onvansertib: A Phase 2 trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with mCRPC who are showing signs of early progressive disease (rise in PSA but minimally symptomatic or asymptomatic) while currently receiving Zytiga® (NCT03414034); a Phase 1b/2 Study of onvansertib in combination with FOLFIRI and Avastin® for second-line treatment in patients with mCRC with a KRAS mutation (NCT03829410); and a Phase 2 clinical trial of onvansertib in combination with decitabine in patients with relapsed or refractory AML (NCT03303339).

Trovagene licensed onvansertib (also known as NMS-1286937 and PCM-075) from Nerviano Medical Sciences (NMS), the largest oncology-focused research and development company in Italy, and a leader in protein kinase drug development. NMS has an excellent track record of licensing innovative drugs to pharma/biotech companies, including Array (recently acquired by Pfizer), Ignyta (acquired by Roche) and Genentech.

About Trovagene, Inc.

Trovagene is a clinical-stage, Precision Cancer Medicine™ oncology therapeutics company developing drugs that target cell division (mitosis), for the treatment of various cancers 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.

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