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): **January 27, 2020**

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 January 27, 2020, Trovagene, Inc. issued a press release announcing positive data from an ongoing Phase 1b/2 clinical trial of onvansertib plus 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 January 27, 2020

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: January 27, 2020

TROVAGENE, INC.

By: /s/ Thomas Adams

Thomas Adams

Chief Executive Officer

Onvasertib Demonstrates Effectiveness as Pan-KRAS Inhibitor with Confirmed Tumor Regression and Clinical Benefit Achieved in KRAS-Mutated mCRC Patients

- ***All patients showed tumor regression by radiographic scan at 8 weeks and confirmation by further tumor shrinkage at 16 weeks; clinical benefit achieved in 100% (n=5) of patients***
- ***Tumor regression occurred across all major KRAS mutation types in CRC, an indication of onvansertib's pan-KRAS inhibitory effect; three patients had a >25% tumor shrinkage***
- ***One patient is proceeding to curative surgery, which is considered to be unprecedented in this patient population with only a 5% response to standard-of care treatment***
- ***KRAS, which is measured with a simple blood test, is a well-established predictor of response; in all patients KRAS levels decreased to undetectable in the 1st cycle of onvansertib treatment***

SAN DIEGO (January 27, 2019) – Trovagene, Inc. (Nasdaq: TROV), a clinical-stage, oncology therapeutics company targeting cancers that are both highly prevalent and in need of new effective treatment options including colorectal, prostate and acute myeloid leukemia, today announced positive data from an ongoing Phase 1b/2 clinical trial of onvansertib plus FOLFIRI and Avastin® (bevacizumab) for second-line treatment of KRAS-mutated metastatic colorectal cancer (mCRC).

The data demonstrate the pan-KRAS inhibitory effect of onvansertib. All five patients evaluable for efficacy assessment have shown a significant reduction in their KRAS mutational burden as measured by a simple blood test, which was subsequently confirmed by tumor regression visible on radiographic scans. Three patients had a >25% tumor shrinkage and one patient is now eligible for curative surgery, a clinically meaningful achievement, which is considered to be unprecedented in this patient population with only a 5% response to standard-of-care. The data was featured in a poster presentation at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI) in San Francisco on Saturday, January 25th, 2020.

Onvansertib is an oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor and may provide an answer to effectively "drugging" the once thought-to-be "undruggable" KRAS mutation. PLK1 has been identified as having synthetic lethality, which means that KRAS-mutated tumors have a higher sensitivity to PLK1 inhibition compared with KRAS wild-type cells.

"Early results from the onvansertib Phase 1b/2 trial are very exciting and encouraging," said Dr. Daniel Ahn, the principal investigator at the Mayo Clinic Cancer Center. "Regardless of the specific KRAS mutation, we are seeing decreases in the mutational burden and tumor regression in all of our patients. This is indicative of onvansertib's effect as a pan-KRAS inhibitor."

"Successfully treating patients in the second-line setting has been quite challenging to-date, with a relatively low response rate and poor prognosis," said another of the trial's investigators, Dr. Tanios Bekaii-Saab, leader of the Gastrointestinal Cancer Program at the Mayo Clinic Cancer Center. "The combination of onvansertib plus standard-of-care FOLFIRI/bevacizumab offers promise as being both safe and effective."

KRAS, which controls cell proliferation, has long been recognized as a major oncogene, responsible for many cancer types. 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. The other KRAS contenders including Amgen and Mirati, have produced some potentially promising early clinical results in non-small cell lung cancer (NSCLC); however, their drug candidates have shown limited activity in CRC as they only address one specific KRAS mutation, G12C, which accounts for only 8% of CRC, leaving room for drug developer, Trovagene, and its drug candidate onvansertib.

Onvansertib KRAS-Mutated mCRC Trial Data Highlights:

- In the Phase 1b dose escalation, the 1st dose level (onvansertib 12 mg/m^2) was cleared for safety; the 2nd dose level (onvansertib 15 mg/m^2) is fully enrolled with no DLTs reported in the two patients treated to-date
- Radiographic scans performed at 8 weeks showed tumor decrease and clinical benefit in 100% (n=5) of evaluable patients treated with onvansertib 12 mg/m^2 (n=5); 1 patient achieved PR, 4 patients achieved SD
- Radiographic responses were confirmed at 16 weeks with further tumor shrinkage in all patients; 3 patients had a >25% decrease; 1 patient is proceeding to curative surgery
- Five different KRAS mutant variants were detected in 6 patients, which represents >90% of KRAS mutations in CRC; all five KRAS variants decreased within the 1st cycle of treatment (onvansertib dose levels 12 and 15 mg/m^2)
- At dose level 1 (onvansertib 12 mg/m^2), 4 patients had detectable KRAS mutant ctDNA at baseline; in all 4 patients KRAS was undetectable within the 1st cycle of treatment; this preceded subsequent tumor shrinkage observed with radiographic scans, supporting the predictive value of liquid biopsy
- At dose level 2 (onvansertib 15 mg/m^2), the 2 patients treated to-date had detectable KRAS mutant ctDNA at baseline; in 1 patient KRAS was undetectable within the 1st cycle of treatment; radiographic scans will be performed at 8 weeks

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

The ongoing 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) is evaluating 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 Cancer Center.

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 solid tumors, leukemias and lymphomas. 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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