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): **July 9, 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 July 9, 2019, Trovagene, Inc. issued a press release announcing the initiation of patient enrollment of its Phase 1b/2 study of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for second-line treatment of patients with metastatic colorectal cancer (mCRC) with a KRAS mutation (NCTO3829410). 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 July 9, 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: July 9, 2019

TROVAGENE, INC.

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

Exhibit 99.1

Trovagene Announces Initiation of Enrollment for Phase 1b/2 Clinical Trial in KRAS-Mutated Colorectal Cancer at Leading Comprehensive Cancer Centers

Trial will evaluate safety and efficacy of onvansertib plus FOLFIRI and Avastin® (bevacizumab) for treatment of patients with KRAS-mutated metastatic Colorectal Cancer (mCRC)

Highly recognized unmet need for 50% of mCRC patients who harbor the KRAS mutation, given current treatment response rate of only 5%

Trovagene to leverage proprietary Precision Cancer Medicine™ tumor genomic technology to assess early indication of treatment response

SAN DIEGO, July 9, 2019 — Trovagene, Inc. (Nasdaq: TROV), a clinical-stage, Precision Cancer Medicine™ oncology therapeutics company, today announced the initiation of patient enrollment of its Phase 1b/2 study of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for second-line treatment of patients with metastatic colorectal cancer (mCRC) with a KRAS mutation (NCT03829410). Trovagene is developing onvansertib, a first-in-class, third-generation, oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor that targets the key master regulator of tumor cell division, for the treatment of leukemias, lymphomas and solid tumor cancers. The trial is being conducted at USC Norris Comprehensive Cancer Center, Hoag Cancer Center and The Mayo Clinic, under the leadership of recognized colorectal cancer key opinion leaders, Heinz-Josef Lenz, MD, FACP, Section Head of GI Oncology and Co-Director of the Colorectal Center at USC Norris, and Afsaneh Barzi, MD, PhD, oncologist at USC Norris and principal investigator of the trial.

“It is well-recognized that there is a significant medical need for better treatment options for KRAS-mutated gastrointestinal cancers,” said Dr. Lenz, who is also a professor of medicine at Keck School of Medicine of USC. “We are targeting these patients in this trial because in onvansertib preclinical studies, tumor cells that harbor KRAS mutations, when treated with onvansertib, have what we call ‘synthetic lethality,’ or in other words, have a greater susceptibility to tumor cell death.”

“We look forward to this trial and the opportunity to examine a potential therapy for a patient population in need of options,” said Dr. Barzi, who is also an associate professor of clinical medicine at the Keck School. “Use of genomic

profiling to understand the molecular underpinnings of mCRC is critical to our precision medicine approach and treating our patients. In addition, KRAS profiling in this trial, by a simple blood test, is anticipated to enable us to get a very early indication of response to treatment. This is key not only for this trial, but for how we can quickly assess response and, in real-time, integrate this approach as part of future patient management."

"Our Phase 1b/2 trial is an opportunity for us to demonstrate the potential for onvansertib to provide a new, safe and efficacious treatment for patients who are faced with a poor prognosis and who have limited therapeutic options," said Thomas Adams, PhD, Chief Executive Officer and Chairman of Trovagene. "Importantly, we have preclinical in-vitro and in-vivo data demonstrating that tumors harboring KRAS mutations are more sensitive to onvansertib-induced tumor death. Furthermore, onvansertib has significant synergy in combination with Camptosar® (irinotecan) and an additive effect with Avastin®, both of which are components of the standard-of-care treatment regimen that will be used in our trial. We are excited to commence this trial, which already has funding in place through a previously announced agreement with PoC Capital, LLC."

About Colorectal Cancer

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 with metastatic disease succumb to the disease. Therefore, improving the treatment options and effectiveness is critical in changing the outcomes for this patient population. KRAS is a common mutation in the CRC population and approximately 50% of patients with CRC carry RAS mutations. In the U.S., FOLFOX (5-flourouracil, leucovorin, oxaliplatin) and FOLFIRI (fluorouracil, leucovorin, irinotecan) are standard-of-care options for patients with metastatic CRC in the first-line setting, irrespective of the KRAS mutation status. The majority of CRC patients respond to first-line therapy with a response rate of > 50%. The efficacy of second-line therapy in terms of survival prolongation and response remains very limited, particularly in the KRAS-mutated population, where treatment options are more restricted. FOLFIRI (a chemotherapy regimen of irinotecan, fluorouracil [5-FU], and leucovorin) + Avastin® (bevacizumab) in the second-line setting is the standard treatment in US. The response rate in the second-line setting is less than 5% as reported in a large international trial of bevacizumab in the second-line setting.

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

In this open-label, Phase 1b/2 trial, onvansertib in combination with standard-of-care FOLFIRI and Avastin® is being evaluated for safety and efficacy. 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 enroll up to 44 patients with a KRAS mutation and histologically confirmed metastatic and unresectable disease. In addition, patients must have failed treatment or be intolerant of FOLFOX (fluoropyrimidine and oxaliplatin) with or without Avastin® (bevacizumab). The trial is being conducted at three prestigious cancer centers: USC Norris Comprehensive Cancer Center, Hoag Cancer Center and The Mayo Clinic.

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 (PLK 1) 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, triple-negative breast cancer (TNBC), as well as other types of cancer.

Trovagene has an ongoing Phase 1b/2 clinical trial of onvansertib in combination with low-dose cytarabine or decitabine in patients with relapsed or refractory AML that was accepted by the National Library of Medicine (NLM) and is now publicly viewable on www.clinicaltrials.gov. The NCT number assigned by clinicaltrials.gov for this study is NCT03303339. Onvansertib has been granted orphan drug designation by the FDA in the U.S. and by the EC in the European Union for the treatment of patients with AML.

Trovagene has an ongoing Phase 2 clinical 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®. The trial was accepted by the NLM and is now publicly viewable on www.clinicaltrials.gov. The NCT number assigned by clinicaltrials.gov for this study is NCT03414034.

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, 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.

About USC Norris Comprehensive Cancer Center

The USC Norris Comprehensive Cancer Center is a leader in cancer research, with more than 200 members investigating the complex origins and progression of cancer, developing prevention strategies and searching for cures. USC Norris is part of the Keck School of Medicine and is designated by the National Cancer Institute as one of the nation’s 45 comprehensive cancer centers.

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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