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 16, 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 8.01 Other Events.

On August 16, 2018, Trovagene, Inc. issued a press release announcing completion of the second dosing cohort of Onvansertib, a first-in-class, 3rd generation, highly-selective oral Polo-like Kinase 1 (PLK1) Inhibitor, in combination with standard-of-care low-dose cytarabine (LDAC), in its Phase 1b/2 clinical trial in patients with Acute Myeloid Leukemia (AML). 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 August 16, 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 16, 2018

TROVAGENE, INC.

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

Trovagene Announces Completion of Second Dosing Cohort of Patients Treated with Onvansertib (PCM-075) in Ongoing Phase 1b/2 AML Trial

Safety Review Committee (SRC) recommends proceeding to the next dose level cohort of Onvansertib in combination with low-dose cytarabine (LDAC) in dose-escalation phase of trial

SAN DIEGO, CA – August 16, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, developing targeted therapies for the treatment of leukemias, lymphomas and solid tumor cancers, today announced completion of the second dosing cohort of Onvansertib, a first-in-class, 3rd generation, highly-selective oral Polo-like Kinase 1 (PLK1) Inhibitor, in combination with standard-of-care low-dose cytarabine (LDAC), in its Phase 1b/2 clinical trial in patients with Acute Myeloid Leukemia (AML).

All three patients in the cohort successfully completed treatment with Onvansertib at 18 mg/m^2, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with LDAC and the combination was well tolerated. The Safety Review Committee (SRC) has recommended escalating to the next dose level of Onvansertib at 27 mg/m^2 (approximately a 50% increase) in combination with LDAC. Additionally, two patients in the three-patient cohort of Onvansertib at 18 mg/m^2 in combination with decitabine have also successfully completed at least one cycle of treatment and recruitment of the third patient to complete this cohort is in process. Four of the eleven patients treated to-date remain on treatment, three are currently receiving a second cycle of treatment and one patient is scheduled to start a fifth cycle of treatment.

“While we are still early in the trial, we are pleased by what we are seeing so far from both a safety and efficacy standpoint,” said Amer Zeidan, MBBS, MHS, assistant professor of Medicine at Yale School of Medicine, Hematology expert at Yale Cancer Center, and lead investigator on the trial. “We did not see any dose limiting toxicities and treatment was well tolerated in the cohort of three patients who were administered Onvansertib at 18 mg/m^2 in combination with LDAC, and the same holds true in the two patients who have completed treatment with Onvansertib at 18 mg/m^2 in combination with decitabine. One of my older patients, who was treated in the initial dosing cohort of Onvansertib at 12 mg/m^2 in combination with decitabine, was enrolled on the trial after he relapsed with AML following previous bone marrow transplantation; a very challenging situation. He is scheduled to start a fifth cycle of treatment with Onvansertib plus decitabine, having achieved a significant reduction in leukemic blast cells in the bone marrow to 18%, clearance of leukemic blast cells in the blood, improvement in his neutrophil count, transfusion independence for both red blood cells and platelets, all of which is consistent with signs of partial remission. He will be able to play in a golf tournament next week, which means a lot to him and is extremely gratifying to us.”

In the Phase 1b segment of this trial, the Onvansertib dose level will be increased by 50% increments in combination with either LDAC or decitabine in successive cohorts of three patients until a maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) is achieved. The MTD or RP2D will be used in the Phase 2 segment of the trial to evaluate antitumor activity and to continue to assess the safety and tolerability of Onvansertib in combination with standard-of-care chemotherapy.

“We are pleased with the progress we are making to identify our Phase 2 dose for the continuation segment of our AML trial, as well as for use in other trials that we may do in the future in hematologic (leukemias/lymphomas) cancers,” said Dr. Mark Erlander, Chief Scientific Officer of Trovagene.

About the Onvansertib Phase 1b/2 Acute Myeloid Leukemia Trial

The Phase 1b/2 trial (NCT03303339) is a multi-center, open-label trial to evaluate the safety and efficacy of Onvansertib in combination with standard-of-care chemotherapy in AML patients who are ineligible for intensive induction therapy or whose disease is relapsed or refractory. In Phase 1b dose-escalation segment of the trial, the primary objective is to determine the maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D), using a traditional 3+3 design. In Phase 2 the MTD or RP2D will be administered to 32 patients to evaluate preliminary antitumor activity and to continue to evaluate the safety and tolerability of Onvansertib in combination with standard-of-care chemotherapy. This trial is being led by Jorge Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center and Amer Zeidan, MBBS, MHS, Assistant Professor of Medicine, Department of Medicine, and Yale Cancer Center, Yale School of Medicine, Yale University. The trial is being conducted at nine sites in the U.S.

About Onvansertib (PCM-075)

Onvansertib is a highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK 1) enzyme, which is over-expressed in multiple hematologic and solid tumor cancers. Separate studies with other PLK inhibitors have shown that inhibition of polo-like-kinases can lead to tumor cell death, including a Phase 2 study in Acute Myeloid Leukemia (AML) where response rates of 31% were observed when used in conjunction with a standard therapy for AML (low-dose cytarabine-LDAC) versus treatment with LDAC alone with a 13.3% response rate. A Phase 1 open-label, dose escalation safety study of Onvansertib has been completed in patients with advanced metastatic solid tumor cancers, and published in *Investigational New Drugs*. The maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) in this trial was 24 mg/m^2. Trovagene has an ongoing Phase 1b/2 clinical trial with Onvansertib in 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 EMA in the European Union (EU) for the treatment of patients with AML.

Onvansertib only targets PLK1 isoform (not PLK2 or PLK3), is oral, has a 24-hour drug half-life with reversible on-target hematologic toxicities. Trovagene believes that targeting only PLK1 with reversible on-target activity and an improved dose/scheduling protocol can significantly improve on the long-term outcome observed in previous studies with a PLK inhibitor in AML.

Onvansertib has demonstrated synergy in preclinical studies with numerous chemotherapeutic and target agents used in leukemias, lymphomas and solid tumor cancers, including FLT3 and HDAC inhibitors, taxanes, and cytotoxins. Trovagene believes the combination of its targeted PLK1 inhibitor, Onvansertib, with other compounds has the potential for improved clinical efficacy in Acute Myeloid Leukemia (AML), metastatic Castration-Resistant Prostate Cancer (mCRPC), Non-Hodgkin Lymphoma (NHL), Triple Negative Breast Cancer (TNBC), as well as other leukemias, lymphomas and solid tumor cancers.

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