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): June 27, 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 June 27, 2018, Trovagene, Inc. issued a press release announcing preliminary clinical data from the first dosing cohort showing a treatment effect with PCM-075 in combination with low-dose cytarabine (LDAC) or decitabine, as measured by decreases in leukemic cells in both peripheral blood and bone marrow in patients in its ongoing Phase 1b/2 trial in relapsed or refractory 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 June 27, 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: June 27, 2018

TROVAGENE, INC.

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

Trovagene Announces Preliminary Clinical Data from First Dosing Cohort Demonstrating Durable Treatment Effect of PCM-075 in Combination with Cytarabine or Decitabine in Patients with Relapsed or Refractory AML

Additional pharmacodynamic data supports inhibition of PLK1 in leukemic cells as measured by pTCTP in its Phase 1b/2 trial in Acute Myeloid Leukemia (AML)

SAN DIEGO, CA – June 27, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, developing targeted therapeutics for the treatment of hematologic and solid tumor cancers, today announced preliminary clinical data from the first dosing cohort showing a treatment effect with PCM-075 in combination with low-dose cytarabine (LDAC) or decitabine, as measured by decreases in leukemic cells in both peripheral blood and bone marrow in patients in its ongoing Phase 1b/2 trial in relapsed or refractory Acute Myeloid Leukemia (AML).

Both blood and bone marrow samples were obtained from patients with relapsed or refractory AML enrolled in the Phase 1b/2 trial prior to, and at timepoints following administration of PCM-075, in combination with cytarabine or decitabine. In the first dose level, seven patients were treated with PCM-075 at 12 mg/m^2 in combination with either LDAC or decitabine. One patient was not evaluable for safety due to rapid disease progression. Among the other 6 patients, no dose-limiting toxicities (DLTs) were observed that would prohibit further escalation of the PCM-075 dosing. Three patients exhibited substantial reductions in the percentage of both circulating leukemic cells within the blood and leukemic cells within the bone marrow. Two of these three patients continued on treatment in the second cycle and further decreases in circulating leukemic cells in the blood and within the bone marrow were observed. One patient had a decrease in his bone marrow blasts from 96% to 40% at the end of cycle 2 and has continued on treatment in cycle 3. The next dose level cohort of PCM-075 at 18 mg/m^2 in combination with LDAC or decitabine is currently enrolling and dosing patients.

In addition, Translational Control Tumor Protein (TCTP), which is uniquely phosphorylated by PLK1, was used to evaluate PLK1 inhibition by PCM-075. Data presented by Trovagene at the 2018 American Association for Cancer Research (AACR) showed that PCM-075 decreases phosphorylated TCTP (pTCTP) in AML cell lines. In these same cell lines pTCTP levels were unaffected by treatment with either LDAC or decitabine.

PLK1 inhibition in the Phase 1b/2 AML trial is being assessed in patients 3-hours following administration of PCM-075 in combination with LDAC or decitabine, when PCM-075 levels are expected to be at their peak concentration (C_{max}). Significant reductions in PLK1, as measured by pTCTP levels, were observed in the circulating blood cells in four of six patients treated with PCM-075 in combination with cytarabine or decitabine. Three of these four patients also had significant reductions in circulating blast cells during the treatment cycle.

“While we are still quite early in the trial, these data points are encouraging from both a safety and efficacy standpoint,” said Amer Zeidan, MBBS, MHS, Assistant Professor of Medicine, Department of Medicine, and Yale Cancer Center, Yale School of Medicine, Yale University, a leading investigator on the trial. “There were no dose limiting toxicities seen in the first cohort and treatment was generally well tolerated. We know that treatment with decitabine or low-dose cytarabine in patients with relapsed or refractory AML is rarely effective, and the rare patients who do respond usually require several cycles of therapy to do so. Seeing substantial blast reductions in blood and bone marrow achieved in several patients in the first one to two cycles at this first dose level of PCM-075, combined with significant reductions in PLK1 activity as measured by pTCTP levels, potentially suggest synergistic clinical activity with the combination therapy. We remain excited to see how our patients will do as we go to higher dose levels of PCM-075.”

“In addition to the preliminary clinical data from our first dose cohort, we are encouraged by the additional pharmacodynamic data for patients in our Phase 1b/2 AML trial,” said Dr. Mark Erlander, Chief Scientific Officer of Trovagene. “This is the first time we have observed a change in PLK1 status in patients during treatment with PCM-075 in combination with either LDAC or decitabine.”

About the PCM-075 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 PCM-075 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 PCM-075 in combination with standard-of-care chemotherapy. This trial is being led by Hematologist 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, New Haven, CT. Nine clinical sites are currently activated in the U.S. and recruiting patients.

About PCM-075

PCM-075 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 up to 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 PCM-075 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 PCM-075 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. PCM-075 has been granted Orphan Drug Designation by the FDA for the treatment of patients with AML. Trovagene is enrolling a Phase 2 trial of PCM-075 in combination with Zytiga® (abiraterone acetate) and prednisone in metastatic Castration-Resistant Prostate Cancer that was accepted by the National Library of Medicine (NLM) and is now publicly viewable on www.clnincaltrials.gov. The NCT number assigned by clinicaltrials.gov for this study is NCT03414034.

PCM-075 only targets the PLK1 isoform (not PLK2 or PLK3), is orally available, 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.

PCM-075 has demonstrated synergy in preclinical studies with over 10 chemotherapeutic and targeted agents used in hematologic and solid tumor cancers, including FLT3 and HDAC inhibitors, taxanes, and cytotoxins. Trovagene believes the combination of its targeted PLK1 inhibitor, PCM-075, 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 hematologic and solid tumor cancers.

About Trovagene, Inc.

Trovagene is a clinical-stage, oncology therapeutics company. The Company’s primary focus is to develop oncology therapeutics for the treatment of hematologic and solid tumor cancers for improved cancer care, utilizing its technology in tumor genomics. 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.

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