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): May 17, 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 May 17, 2018, Trovagene, Inc. issued a press release announcing the completion of the first dose cohort in its Phase 1b/2 clinical trial of PCM-075, a highly-selective Polo-like Kinase 1 (PLK1) Inhibitor, in combination with LDAC, in 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 May 17, 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: May 17, 2018

TROVAGENE, INC.

By: /s/ William J. Welch
William J. Welch
President and Chief Executive Officer

Trovagene Announces Completion of First Dosing Cohort of Patients in Ongoing Phase 1b/2 Trial of PCM-075 in Acute Myeloid Leukemia

Safety Review Committee (SRC) recommends proceeding to the second dosing cohort of PCM-075 in combination with low-dose cytarabine (LDAC) in dose-escalation phase of trial

SAN DIEGO, CA – May 17, 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 the completion of the first dose cohort in its Phase 1b/2 clinical trial of PCM-075, a highly-selective Polo-like Kinase 1 (PLK1) Inhibitor, in combination with LDAC, in Acute Myeloid Leukemia (AML).

Three patients were treated with PCM-075 at 12 mg/m^2, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with LDAC. Patients eligible for Phase 1b have relapsed or refractory disease and may have received as many as three prior regimens for treatment of their AML. The combination of PCM-075 and LDAC was well tolerated in all patients. The independent Safety Review Committee (SRC) has recommended escalating to the second dose cohort of three patients at PCM-075 at 18 mg/m^2 (approximately a 50% increase) in combination with LDAC. The PCM-075 dose level may be increased by 50% increments 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 PCM-075 in combination with standard-of-care chemotherapy.

“We are pleased that the combination of PCM-075 and LDAC was well tolerated and that the SRC recommended we advance to our second dose cohort,” said Bill Welch, Chief Executive Officer of Trovagene. “Investigator interest in our development program is high and we are encouraged by the steady activity across our eight activated clinical sites to identify patients.”

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. Eight of ten 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.

PCM-075 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.

PCM-075 has demonstrated synergy in preclinical studies with over 10 chemotherapeutic and target 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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