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): March 5, 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 March 5, 2018, Trovagene, Inc. issued a press release announcing that the initial patient completed the first cycle 1 of treatment in its Phase 1b/2 multicenter trial of PCM-075 in combination with low-dose cytarabine (LDAC) 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 March 5, 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: March 5, 2018

TROVAGENE, INC.

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

Trovagene Announces First Patient Successfully Completes Cycle 1 of Treatment with PCM-075 in Combination with Low Dose Cytarabine (LDAC) in AML Trial

SAN DIEGO, CA – March 5, 2018 — Trovagene, Inc. (NASDAQ: TROV), a precision medicine biotechnology company, developing targeted cancer therapeutics, today announced that the initial patient completed the first cycle 1 of treatment in its Phase 1b/2 multicenter trial of PCM-075 in combination with low-dose cytarabine (LDAC) in patients with Acute Myeloid Leukemia (AML). The patient tolerated the combination well and correlative analyses of blood samples, taken at specified time points, also indicated activity on leukemic blood cells.

A significant decrease in the percentage of blood leukemic cells was observed within 24 hours of administering PCM-075 + LDAC. By day 15, within the treatment cycle, the greatest effect was observed with blood leukemic cells showing a decrease from greater than 40% to less than 5%. Additionally, the same tumor DNA mutations (ASXL1 and SRSF2) were detected in the bone marrow and blood, indicating consistency across samples and validity of the analyses. Both DNA mutations appeared to quantitatively track with the decrease in blood leukemic cells.

“Our first patient on PCM-075 appears to be tolerating the drug regimen well and the observed decrease of blood leukemic cells during the treatment cycle is encouraging,” said Alex Spira, MD, PhD, FACP, Director of The Virginia Cancer Specialists Research Institute.

“We are pleased to see our AML trial off to such a great start,” said Bill Welch, Chief Executive Officer of Trovagene. “With six clinical trial sites open and actively screening and enrolling patients, including MD Anderson Cancer Center, Virginia Cancer Specialists, Kansas University Cancer Center, Yale Cancer Center, Virginia Piper Cancer Institute and UCLA, we anticipate increasing enrollment in the coming weeks and look forward to sharing additional data as it becomes available.”

The Phase 1b/2 trial is a multi-center, open-label trial exploring 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. 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.

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. Studies 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*. Trovagene is initiating a 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 PLK-1 inhibitor, PCM-075, with other compounds has the potential for improved clinical efficacy in Acute Myeloid Leukemia (AML), Castration-Resistant Prostate Cancer (CRPC), Non-Hodgkin Lymphoma (NHL), Triple Negative Breast Cancer (TNBC) and Adrenocortical Carcinoma (ACC).

About Acute Myeloid Leukemia

Acute myeloid leukemia (AML) is a hematologic malignancy in which myeloid lineage cells of the bone marrow cease to differentiate appropriately, resulting in a marked increase in the number of circulating immature blast cells. As a consequence, the counts of mature red blood cells, platelets, and normal white blood cells decline, causing fatigue, shortness of breath, bleeding, and increased susceptibility to infection. The Surveillance, Epidemiology and End Results (SEER) program estimates the annual incidence rate of AML in the United States to be approximately 21,000 cases in 2017. Rates of new AML cases have been rising an average of 3.1% each year over the last 10 years. The median age of AML diagnosis is 68 years of age, and approximately 45% of new diagnoses are among patients age 70 years or older

About Trovagene, Inc.

Trovagene is a precision medicine biotechnology company developing oncology therapeutics for improved cancer care by leveraging its proprietary Precision Cancer Monitoring® (PCM) technology in tumor genomics. Trovagene has broad intellectual property and proprietary technology to measure circulating tumor DNA (ctDNA) in urine and blood to identify and quantify clinically actionable markers for predicting response to cancer therapies. Trovagene offers its PCM technology at its CLIA/CAP – accredited laboratory and plans to continue to vertically integrate its PCM technology with precision 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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