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 1, 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 1, 2018, Trovagene, Inc. issued a press release announcing that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has adopted a positive opinion recommending PCM-075 for designation as an orphan medicinal product for the treatment of 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 1, 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 1, 2018

TROVAGENE, INC.

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

Exhibit 99.1

Trovagene Receives Positive Opinion for Orphan Drug Designation in the European Union for PCM-075, Trovagene's Investigational Cancer Drug

SAN DIEGO, CA – August 1, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, developing targeted therapeutics for the treatment of leukemias/lymphomas and solid tumor cancers, today announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has adopted a positive opinion recommending PCM-075 for designation as an orphan medicinal product for the treatment of Acute Myeloid Leukemia (AML). PCM-075 is a first-in-class, 3rd generation, highly selective, oral Polo Like Kinase 1 (PLK1) inhibitor, that is designed to target cell division (mitosis).

"This positive opinion from the EMAs Committee for Orphan Medicinal Products, based on our in vivo data supporting medical plausibility and the potential for significant benefit of PCM-075, marks another milestone in our efforts to improve the lives of patients suffering from AML," said Dr. Thomas Adams, Chairman and Interim Chief Executive Officer of Trovagene. "We believe that PCM-075, in combination with standard-of-care chemotherapies and targeted therapeutics, has the potential to provide significant clinical benefit with regard to efficacy and safety in patients with AML and we remain keenly focused on advancing our ongoing multi-center Phase 1b/2 clinical trial."

To be considered for Orphan Drug Designation in the EU, companies must provide data that demonstrates plausibility for use of the investigational therapy in the treatment of the disease and establish that the drug has the potential to provide relevant advantages or a major contribution to patient care over existing therapies. The opinion letter sent to Trovagene by the COMP stated that "although satisfactory methods of treatment of the condition have been authorized in the EU, PCM-075 will be of significant benefit to those affected by AML."

The COMP, a committee of the EMA, adopts an opinion on the granting of orphan drug designation, after which the opinion is submitted to the European Commission for endorsement of the opinion. The positive opinion issued by the COMP is anticipated to be adopted by the European Commission (EC) at the end of August 2018.

Orphan drug designation by the European Commission provides regulatory and financial incentives for companies to develop and market therapies to treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union (EU), and where no satisfactory treatment is available. Among the incentives available to therapeutics designated as orphan drugs by the EC are ten-year market exclusivity in the EU after product approval, eligibility for conditional marketing authorization, protocol assistance from the EMA at reduced fees during the product development phase and direct access to centralized marketing authorization in the EU.

About Acute Myeloid Leukemia (AML)

Acute myeloid leukemia (AML) is an aggressive 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 incidence is estimated to be approximately 18,000 new cases annually in the EU and is on the rise due to the aging population. The five-year survival rate is approximately 22%.

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 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, 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