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 29, 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 29, 2018, Trovagene, Inc. issued a press release announcing that the European Commission (EC) has endorsed the positive opinion of the Committee for Orphan Medicinal Products (COMP) and has granted Orphan Drug Designation (ODD) for Onvansertib, a first-in-class, 3rd generation, oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor, for the treatment of 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 29, 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 29, 2018

TROVAGENE, INC.

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

Trovagene Announces European Commission Grants Orphan Drug Designation to Onvansertib (PCM-075) for Treatment of Acute Myeloid Leukemia in Europe

SAN DIEGO, CA – August 29, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, using a precision medicine approach to develop drugs for the treatment of leukemias, lymphomas and solid tumor cancers, today announced that the European Commission (EC) has endorsed the positive opinion of the Committee for Orphan Medicinal Products (COMP) and has granted Orphan Drug Designation (ODD) for Onvansertib, a first-in-class, 3rd generation, oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor, for the treatment of patients with Acute Myeloid Leukemia (AML).

“The European Commission’s decision to grant orphan drug designation to Onvanersertib for the treatment of AML is a key regulatory milestone that will further facilitate our clinical development program,” said Dr. Thomas Adams, Executive Chairman of Trovagene. “We believe that Onvansertib, which previously received orphan drug designation for the treatment of AML from the FDA in the U.S., has the potential to provide a much-needed new therapeutic option for patients who are ineligible for induction therapy or who have relapsed/refractory disease.”

Orphan drug designation by the EC provides regulatory and financial incentives to Trovagene, including reduced fees during the product development phase, direct access to centralized marketing authorization in the EU, and 10-year market exclusivity following product approval.

The COMP, a committee of the EMA, adopted a positive opinion on the granting of orphan drug designation to Onvansertib in July, 2018, stating that “Onvansertib will be of significant benefit to those affected by AML.” Following the process set forth by the EMA, the opinion of the COMP was subsequently submitted to the European Commission (EC) for formal endorsement. The EC decision to endorse the positive opinion issued by the COMP was received by Trovagene on August 28, 2018.

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 Onvansertib (formerly known as PCM-075)

Onvansertib is a first-in-class, 3rd generation, oral and highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK 1) enzyme, which is over-expressed in multiple cancers, including leukemias, lymphomas and solid tumors. 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 up to 31% were observed when combined 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 EC in the European Union (EU) for the treatment of patients with AML. Trovagene is also enrolling a Phase 2 trial of Onvansertib in combination with Zytiga® (abiraterone acetate) and prednisone in metastatic Castration-Resistant Prostate Cancer (mCRPC) 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.

Onvansertib targets the PLK1 isoform (not PLK2 or PLK3), is orally available, has a 24-hour drug half-life with only mild to moderate side effects reported. Trovagene believes that targeting only PLK1 and having a favorable safety and tolerability profile, along with an improved dose/scheduling regimen will significantly improve on the outcome observed in previous studies with a former panPLK inhibitor in AML.

Onvansertib has demonstrated synergy in preclinical studies with numerous chemotherapies and targeted therapeutics used to treat 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 to improve 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 types of cancer.

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.

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