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): April 1, 2019

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 April 1, 2019, Trovagene, Inc. (the "Company") issued a press release announcing the presentation of new data at the American Association for Cancer Research (AACR) 2019 Annual Meeting from its ongoing Phase 1b/2 study evaluating onvansertib in combination with standard-of-care chemotherapy 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 April 1, 2019

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: April 1, 2019

TROVAGENE, INC.

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

Phase 1b/2 Dose Escalation Trial of Onvansertib in Relapsed/Refractory AML Demonstrates Safety, Tolerability and Relative Durability with Complete Responses at Highest Dose Levels

Greatest anti-leukemic activity has been observed in the onvansertib + decitabine arm, with complete response in 2 of 4 (50%) of evaluable patients from the two highest dose levels

No Dose Limiting Toxicities Observed to-date

Two-thirds of patients have completed ³2 cycles of treatment

2 patients currently on treatment for more than 11 and 5 months, respectively

Significant association observed between biomarker-positive patients and response to onvansertib

SAN DIEGO, CA – April 1, 2019 – Trovagene, Inc. (Nasdaq: TROV), a clinical-stage oncology therapeutics company, taking a precision medicine approach to develop drugs that target cell division (mitosis) for the treatment of leukemias, lymphomas and solid tumor cancers, today presented new data from its ongoing Phase 1b/2 study evaluating onvansertib in combination with standard-of-care chemotherapy in Acute Myeloid Leukemia (AML).

The data, featured at the American Association for Cancer Research (AACR), demonstrates the safety, tolerability, preliminary efficacy and relative durability of response in patients treated with onvansertib, in combination with either low-dose cytarabine (LDAC) or decitabine, in patients with relapsed/refractory acute myeloid leukemia (AML). The prognosis for these patients is poor with short survival time and limited treatment options. Onvansertib is a first-in-class, 3rd generation, highly-selective oral Polo-like Kinase 1 (PLK1) Inhibitor that is being evaluated in an ongoing Phase 1b/2 clinical trial at nine sites in the U.S.

Presentation Highlights

Anti-Leukemic Activity:

- Objective response rate (anti-leukemic activity) has been observed at last 3 highest dose levels of onvansertib with 5 of 19 evaluable patients achieving a complete response (CR and CRi, 2 patients); a morphologic leukemic-free state (MLFS, 2 patients); and a partial response (PR, patient). Furthermore, stable disease (SD) was observed in 12 patients.
- The greatest anti-leukemic activity has been observed in the onvansertib + decitabine arm, with 2 of 4 (50%) evaluable patients from the two highest dose levels tested to-date (27mg/m^2 and 40mg/m^2) achieving a complete response (CR and CRi)
- Early indication of safety, tolerability and durability of response has been demonstrated by 16 of 24 patients who have completed ³2 cycles of treatment, including 2 patients who have been on treatment for 11.5 months (patient with PR) and 5.4 months (patient with CRi)

Biomarker Analysis:

- Positive biomarker status to-date (the phosphorylation of translational control tumor protein (pTCTP), which is a specific marker for PLK1 activity, has been observed in 8 out of 22 patients (33%) and has been associated with a statistically significant greater response to treatment (p=0.019)

Safety/Tolerability:

- There have been no dose-limiting toxicities through the completed dose level of 40mg/m^2
- No serious adverse events (SAEs) reported to-date have been considered related to onvansertib

“While we are still in the dose escalation part of the trial, the preliminary efficacy data is encouraging, in particular that we are seeing some complete and relatively durable responses,” said Dr. Amer Zeidan, lead investigator and assistant professor of Medicine at Yale School of Medicine, and Hematology expert at Yale Cancer Center. “AML patients with relapsed or refractory disease have short survival time and very limited treatment options. As we continue to dose escalate through the Phase 1b trial, we are not only encouraged by how safe and well-tolerated onvansertib appears to be thus far in this patient population, but also by the evidence of clinical activity we are seeing especially with the decitabine-based combination at the higher doses of onvansertib. For example, one of my patients, who responded to treatment, is nearly one year out from the time of enrollment in this trial and continues to do quite well. We hope, as we continue in the trial and reach the recommended Phase 2 dose, that we will see additional evidence of clinical efficacy.”

Details of the poster presentation are provided below:

Title: ***Phase 1b Safety, Preliminary Anti-Leukemic Activity and Biomarker Analyses of the Polo-like Kinase 1 (PLK1) Inhibitor, Onvansertib, in Combination with Low-Dose Cytarabine (LDAC) or Decitabine in Patients with Relapsed/Refractory Acute Myeloid***

Session Title: Phase I-III Trials in Progress: Part 1

Date and Time: Monday, April 1, 2019; 1:00 PM - 5:00 PM EST

Session Location: Georgia World Congress Center, Exhibit Hall B, Poster Section 17

About the Ongoing Onvansertib 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 Onvansertib 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 Onvansertib in combination with standard-of-care chemotherapy. This trial is being led by Amer Zeidan, MBBS, MHS, assistant professor of Medicine at Yale School of Medicine, and Hematology expert at Yale Cancer Center, and Jorge Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center. The trial is being conducted at nine sites in the U.S.

About Onvansertib

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.

Onvansertib targets the PLK1 isoform, only (not PLK2 or PLK3), is orally administered, 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), Colorectal Cancer, Triple Negative Breast Cancer (TNBC), as well as other types of cancer.

About Trovagene, Inc.

Trovagene is a clinical-stage, oncology therapeutics company, taking 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. 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, 2018, 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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