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): February 28, 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 February 28, 2019, Trovagene, Inc. (the "Company") issued a press release announcing that two abstracts, highlighting data from the Company's lead clinical programs of onvansertib in Acute Myeloid Leukemia (AML) and metastatic Castration-Resistant Prostate Cancer (mCRPC), respectively, have been accepted for presentation at the American Association for Cancer Research (AACR) Annual Meeting, March 29 - April 3, 2019 in Atlanta, GA. 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 February 28, 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: February 28, 2019

TROVAGENE, INC.

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

Trovagene to Present Data from Lead Clinical Programs of Onvansertib in AML and mCRPC at the American Association for Cancer Research Annual Meeting

SAN DIEGO, CA – February 28, 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 announced that two abstracts, highlighting data from the Company's lead clinical programs of onvansertib in Acute Myeloid Leukemia (AML) and metastatic Castration-Resistant Prostate Cancer (mCRPC), respectively, have been accepted for presentation at the American Association for Cancer Research (AACR) Annual Meeting, March 29 - April 3, 2019 in Atlanta, GA.

The poster scheduled for presentation on Monday, April 1, 2019, will include safety and preliminary anti-leukemic activity data from the ongoing Phase 1b/2 clinical trial of onvansertib, a first-in-class, 3rd generation, highly-selective oral Polo-like Kinase 1 (PLK1) Inhibitor, in combination with standard-of-care low-dose cytarabine (LDAC) or decitabine in patients with relapsed or refractory AML. The first three dose escalation cohorts (12mg/m^2, 18mg/m^2 and 27mg/m^2) have been completed with no patients experiencing dose-limiting toxicities and the fourth dose level (40mg/m^2) is fully enrolled.

The poster scheduled for presentation on Tuesday, April 2, 2019, will feature safety and initial efficacy data from the ongoing Phase 2 clinical trial of onvansertib in combination with Zytiga (abiraterone acetate)/prednisone in patients with mCRPC. The safety lead-in of three patients showed no dose-limiting toxicities or new toxicities from the combination regiment. A 29-patient expansion phase is ongoing, with 11 patients enrolled as of February, 2019. Also, a second arm with a shortened dosing schedule of 14-days is being added to the trial and will enroll 32 additional patients. Patients will be alternately assigned to one of the two arms.

"We continue to be encouraged by the demonstrated safety and clinical benefit of onvansertib that we are seeing in our two ongoing clinical trials," said Dr. Thomas Adams, Chief Executive Officer of Trovagene. "As open-label trials we plan to provide data readouts throughout the year, as well as sharing updates on our biomarker strategy that will enable us to identify patients who are most likely to respond to treatment with onvansertib."

Details of the poster presentations are provided below:

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

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

Session 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

Poster Board Number: 1

Abstract Number: CT102

About the Ongoing Onvansertib Phase 1b/2 Trial in AML

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 have relapsed or refractory disease. 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 Jorge Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center and Amer Zeidan, MBBS, MHS, assistant professor of Medicine at Yale School of Medicine, and Hematology expert at Yale Cancer Center. The trial is being conducted at nine sites in the U.S.

Title: ***A Phase 2 Study of the Polo-like Kinase 1 (PLK1) Inhibitor Onvansertib in Combination with Abiraterone (abi) and Prednisone in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC)***

Session Title: Phase I-III Trials in Progress: Part 2

Session Date and Time: Tuesday, April 2, 2019; 8:00 AM - 12:00 PM EST

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

Poster Board Number: 5

Abstract Number: CT161

About the Ongoing Onvansertib Phase 2 Trial in mCRPC

In this multi-center, open-label, Phase 2 trial, onvansertib in combination with the standard dose of Zytiga® (abiraterone acetate) and prednisone, all administered orally, is being evaluated for safety and efficacy. The trial will enroll up to 45 patients with mCRPC showing early signs of disease progression demonstrated by two rising PSA values separated by at least one week, while on Zytiga®/prednisone therapy. The primary efficacy endpoint is the proportion of patients achieving disease control after 12 weeks of study treatment, as defined by lack of prostate specific antigen (PSA) progression in patients who are showing signs of early progressive disease (rise in PSA but minimally symptomatic or asymptomatic) while currently receiving abiraterone acetate and prednisone (NCT03414034). The trial is being conducted at Beth Israel Deaconess Medical Center (BIDMC), Dana Farber Cancer Institute (DFCI) and Massachusetts General Hospital (MGH).

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.trovageneoncology.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, 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, Investor Relations and Corporate Communications
858-952-7652
vkelemen@trovagene.com