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 14, 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 14, 2019, Trovagene, Inc. issued a press release announcing the presentation of an overview of its ongoing Phase 2 study evaluating Onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC) at the Genitourinary Cancers Symposium (ASCO-GU) in San Francisco, CA. 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 14, 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 14, 2019

TROVAGENE, INC.

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

Trovagene Presents Update on Phase 2 Study of Onvansertib in Combination with Zytiga in Patients with mCRPC at ASCO-GU Conference

Safety lead-in completed, no overlapping toxicities, combination is safe and well tolerated

Expanding trial to include alternate dosing schedule to maximize observed clinical activity

SAN DIEGO, CA – February 14, 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 an overview of its ongoing Phase 2 study evaluating Onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC) at the Genitourinary Cancers Symposium (ASCO-GU) in San Francisco, CA.

The data, featured in a poster presentation at the Genitourinary Cancers Symposium (ASCO-GU), demonstrates the safety and tolerability of Onvansertib in combination with Zytiga®, confirmed in the safety lead-in that was completed prior to opening the trial to full enrollment. In addition, a second arm is planned with the goal of maximizing clinical activity by reducing the dosing schedule from the current 21-days to 14-days.

“We are pleased with the progress we are making in our Phase 2 mCRPC trial and to having our lead investigator, Dr. David Einstein, of Beth Israel Deaconess Medical Center, present the poster at the ASCO-GU conference today,” said Dr. Thomas Adams, Chief Executive Officer and Chairman of Trovagene. “There are limited options, other than intensive chemotherapy which has a poor prognosis, in patients who are showing initial signs of resistance to treatment with Zytiga®. The objective of our trial is to demonstrate clinical benefit by lowering or stabilizing levels of prostate specific antigen (PSA) with the combination of onvansertib and Zytiga®. We believe the combination regimen may provide a much-needed new therapeutic option for these patients.”

Details of the poster presentation are provided below:

Title: ***A Phase 2 Study of Onvansertib (PCM-075) in Combination with Abiraterone and Prednisone in Patients with Metastatic Castration-Resistant Prostate Cancer***

Session Name: Trials in Progress Poster Session A: Prostate Cancer

Location: Moscone West Building—Poster Board N12—Abstract TPS336

Date and Time: Thursday, February 14, 2019: 11:30 AM—1:00 PM and 5:30 PM—6:30 PM

Presentation Highlights:

Background

- Polo-like Kinase 1 (PLK1):

- Serine/threonine kinase, master regulator of cell-cycle progression
- Overexpressed in prostate cancer
- Androgen Receptor (AR) and PLK1 regulate each other
- PLK1 synergy with Zytiga® (abiraterone acetate) identified in a novel in-vivo castration-resistant prostate cancer (CRPC) model

- Onvansertib (also known as PCM-075 and NMS-1286937):
  - Orally-bioavailable, highly-selective PLK1 inhibitor
  - ~24-hour half-life
  - Induces G2/M arrest and apoptosis in cancer cells, including prostate cancer
  - Safe and well tolerated
  - Recommended Phase 2 dose established

Safety Endpoint

- Safety and tolerability confirmed in safety lead-in patients; no overlapping toxicities; trial fully enrolling

Efficacy Endpoint

- Observe effects of onvansertib in combination with Zytiga on disease control rate (Prostate Specific Antigen [PSA] decline of stabilization in patients with mCRPC and early resistance to Zytiga

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.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, 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
Vice President Clinical Development
858-952-7652
vkelemen@trovagene.com