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): December 3, 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 December 3, 2018, Trovagene, Inc. (the "Company") issued a press release announcing that it has presented updated data from its ongoing Phase 1b/2 study evaluating Onvansertib in combination with standard-of-care chemotherapy in Acute Myeloid Leukemia (AML) in a poster presentation at the 60th American Society of Hematology (ASH) Annual Meeting. 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 December 3, 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: December 3, 2018

TROVAGENE, INC.

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

New Data from Phase 1b/2 Study of Onvansertib in Combination with LDAC or Decitabine Demonstrates Response to Treatment in Relapsed/Refractory AML

- ***Preliminary Anti-Leukemic Activity Demonstrates >80% Response to Treatment with Onvansertib in Combination with Low-Dose Cytarabine (LDAC) or Decitabine in Dose Escalation Phase 1b of Trial***

- ***Onvansertib is Safe and Well-Tolerated with No Drug-Related Severe Adverse Events Reported to-date***

SAN DIEGO, CA – December 3, 2018 – 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 updated 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 in a poster presentation at the 60th American Society of Hematology (ASH) Annual Meeting, demonstrate that Onvansertib, in combination with LDAC or decitabine, even at the dose-escalation phase of the trial, is benefiting patients who have relapsed/refractory Acute Myeloid Leukemia (AML), and that the combination regimen is safe and well-tolerated, with no serious adverse events (SAEs) reported to-date. 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.

AML is a rapidly progressing bone marrow cancer with poor survival rates compared to other leukemias. The standard of care for people with AML is intensive chemotherapy; however, for many elderly patients with AML intensive treatment is not an option. Additionally, patients with relapsed or refractory AML remain among the most challenging to treat and prognosis is poor.

“AML patients with relapsed/refractory disease have very limited, if any, treatment options,” said Dr. Amer Zeidan, lead investigator and assistant professor of Medicine at Yale School of Medicine, and Hematology expert at Yale Cancer Center. “While we are still early in the trial where patients are being treated in the dose escalation phase, we are encouraged by the safety profile of onvansertib. Importantly, there are signs of preliminary efficacy we are already seeing in the dose escalation phase of the trial of onvansertib in combination with decitabine or low dose cytarabine. One patient has achieved an ongoing partial response; showing a significant reduction in blast count and hematologic count improvement, while 9 patients so far have stable disease. AML, especially when relapsed or refractory, is a biologically aggressive cancer, so prolonged periods of stable disease are considered clinically meaningful. We anticipate as we continue in the trial and reach the recommended Phase 2 dose that we will see additional evidence of clinical efficacy.”

“A key component of our Onvansertib clinical development program is the integration of a predicative biomarker strategy to help identify patients who are more likely to respond to treatment,” said Dr. Mark Erlander, Chief Scientific Officer of Trovagene. “Thus far we have observed a rapid and durable inhibition of the PLK1 enzyme by Onvansertib in a subset of patients, which is also associated with a higher response to treatment, as measured by decreases in circulating and bone marrow leukemic blast cells. We believe this will provide a significant advantage as we advance our clinical trial in AML, and other cancers, and will enable us to select sub-populations of patients who will benefit most from treatment with Onvansertib.”

Presentation Highlights:

Background

- Polo-like Kinase 1 (PLK1):
  - Serine/threonine kinase, master regulator of cell-cycle progression
  - Inhibition of PLK1 causes mitotic arrest in prometaphase and subsequent cell death
  - Over-expressed in numerous cancer types, including AML, and associated with poor prognosis
  - A pan-PLK inhibitor, volasertib in combination with LDAC, improved survival in a randomized Phase 2 trial in AML
  - A 3rd generation PLK1 inhibitor (Onvansertib), with increased specificity, potency and pharmacologic properties was needed to optimize features that hampered future development of volasertib
- 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 leukemic cells
  - Demonstrates synergy in combination with chemotherapies and targeted therapeutics
  - Safe and well tolerated (Phase 1 dose escalation trial in patients with solid tumors)

Safety

- No trial therapy-related deaths
- No Severe Adverse Events (SAEs) were considered related to study drug treatment
- AE possibly related to Onvansertib was Grade 1 nausea in 4 patients

Preliminary Efficacy

- Of the 19 patients evaluable for safety, 12 patients had an evaluable bone marrow biopsy to assess anti-leukemic activity based on criteria from the 2017 ELN recommendations
- Of the 12 patients evaluated for preliminary anti-leukemic activity, 1 patient had a partial response (PR), 9 patients had stable disease (SD) and 2 patients had progressive disease (PD)

Conclusions and Perspective

- Two dose-levels of Onvansertib (12 mg/m^2 and 18 mg/m^2) were completed, with 13 patients evaluable for safety

- 6 patients have been enrolled at the 27 mg/m^2 dose-level, 3 have finished cycle 1 without experiencing dose-limiting toxicities (DLTs); 3 patients are on cycle 1 of treatment
- Preliminary efficacy in the evaluable population showed over 80% patient benefit (CR + PR + SD): 1 patient with PR, 9 patients with SD
- PLK1 inhibition by treatment was observed in 5 out of 15 patients and was associated with a higher response to treatment, measured by decreases in circulating and bone marrow blasts
- Implementation of a pTCTP biomarker strategy going forward will increase the opportunity to identify patients most likely to respond to Onvansertib
- No drug-related deaths or SAEs have been reported to-date

Details of the poster presentation are provided below:

Title: *Phase 1b Preliminary Safety and 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 Leukemia*

Session Name: Session 616. Acute Myeloid Leukemia: Novel Therapy, Excluding Transplantation: Poster III

Location: Hall GH (San Diego Convention Center)

Date and Time: Monday, December 3, 2018; 6:00 PM - 8:00 PM

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 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.

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.

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