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 9, 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	TROV	Nasdaq Capital Market

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:

o Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

Item 8.01 Other Events.

On December 9, 2019, Trovagene, Inc. (the "Company") issued a press release announcing the presentation of final results from the Company's Phase 1b study of onvansertib in patients with relapsed/refractory acute myeloid leukemia (AML) in an oral session at the American Society of Hematology (ASH) annual conference in Orlando, FL, on Saturday, December 7th. 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 9, 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: December 9, 2019

TROVAGENE, INC.

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

Efficacy, Durability of Response and Safety of Onvansertib Demonstrated in Completed Phase 1b Trial in AML Patients Presented in Oral Session at ASH

- ***Efficacy observed at onvansertib doses ranging from 27 to 90 mg/m^2 with a complete response (CR) and CR with incomplete count recovery (CRi) rate of 31% (5/16)***
- ***Four patients remain on treatment and in remission; to-date duration of response up to 1 year***
- ***Treatment was well tolerated; adverse events related to onvansertib were primarily on-target hematological (based on mechanism of action) and were easily managed and reversible***
- ***Biomarker positive patients showed a higher response to treatment; 67% (4/6) of patients had marked decreases in bone marrow blast cells vs only 18% (1/11) biomarker negative patients***

SAN DIEGO (December 9, 2019) – Trovagene, Inc. (Nasdaq: TROV), a clinical-stage, Precision Cancer Medicine™ oncology therapeutics company developing drugs that target cell division (mitosis), for the treatment of various cancers including leukemia, prostate and colorectal, today announced the presentation of final results from the Company's Phase 1b study of onvansertib in patients with relapsed/refractory acute myeloid leukemia (AML) in an oral session at the American Society of Hematology (ASH) annual conference in Orlando, FL, on Saturday, December 7th. The presentation highlighted the efficacy, durability of response, favorable safety and tolerability profile, as well as correlative biomarker data from the recently completed Phase 1b trial.

The oral presentation at ASH is available for download from the Scientific Presentations page on the Trovagene website at https://trovageneoncology.com/scientific-presentations/.

"I am encouraged by the preliminary efficacy and safety/tolerability demonstrated in the dose escalation part 1b of our trial," said Dr. Amer Zeidan, lead investigator and associate professor of Medicine at the Yale School of Medicine, and Hematology expert at Yale Cancer Center. "As we continue with enrollment and assessment of efficacy in the Phase 2 portion of the trial, I look forward to seeing additional clinical benefit of onvansertib in combination with decitabine in our relapsed and refractory AML patients."

Oral Presentation Highlights

Background:

- Onvansertib is an oral, highly-selective Polo-like Kinase 1 (PLK1) inhibitor with a half-life of ~24 hours
- PLK1 inhibition by onvansertib, assessed via a simple blood test and shown as changes in the phosphorylation of its direct substrate, the translational controlled tumor protein, TCTP, is a biomarker for identifying patients most likely to respond to treatment
- Patients eligible for enrollment in the Phase 1b trial were treatment naïve and not candidates for induction therapy or had relapsed/refractory disease to up to 3 prior regimens (Phase 1b)

Treatment Summary as of October 31, 2019

Safety and Tolerability:

- Treatment was well tolerated through the first 5 dose escalation cohorts (onvansertib 12 - 60 mg/m^2)
- 9 of the 71 SAEs (13%) were considered as possibly related to onvansertib and occurred at the higher dose levels: 40 mg/m^2 (1), 60 mg/m^2 (1) and 90 mg/m^2
- The maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) was established at 60 mg/m^2

Preliminary Efficacy:

- 6 (17%) patients had a complete response (CR, CRi); 9 (25%) had an ORR (CR, CRi, MLFS, PR) across LDAC and decitabine arms and doses
- At the 4 higher dose levels (27 to 90 mg/m^2), CR/CRi was observed in:
    - 5 (31%) of the 16 patients in the decitabine Arm
    - 1 (11%) of the 9 patients in the LDAC Arm
- Median time to achieve CR/CRi was 4 cycles (range 1-7)
- Median duration of response was 5 months (range 0-11.5)
- 4 of 6 patients remain on treatment and in remission; duration of CR/CRi is respectively 1.5, 7, 8 and 11.5 months

Biomarker Analysis:

- Of the 24 evaluable patients, 8 (33%) were biomarker positive across both arms
- Among patients with at least 1 BM biopsy (n=17), biomarker positivity was associated with higher response to treatment:
    - 67% of biomarker positive patients (4/6) had a ≥20% decrease in blasts versus 18% in biomarker negative patients (1/11)
    - CR/CRi was achieved in 2 biomarker positive patients but in none of the biomarker negative patients

About the Phase 2 Clinical Trial of Onvansertib in AML

The Phase 2 AML trial (NCT03303339) of onvansertib in combination with decitabine will enroll 32 patients who are either treatment naïve and not candidates for induction therapy or who have relapsed disease after treatment with one prior regimen. Patients will receive onvansertib,

administered orally, on days 1 through 5 of each 21-28-day cycle in combination with decitabine. The primary efficacy endpoint of objective response (CR + CRi) will be assessed in patients who complete at least 1 cycle of treatment.

About Onvansertib

Onvansertib is a first-in-class, third-generation, oral and highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK1) enzyme, which is over-expressed in multiple cancers including leukemias, lymphomas and solid tumors. Onvansertib targets the PLK1 isoform only (not PLK2 or PLK3), is orally administered and has a 24-hour 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 irinotecan, FLT3 and HDAC inhibitors, taxanes and cytotoxins. Trovagene believes the combination of 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 and triple-negative breast cancer (TNBC), as well as other types of cancer.

Trovagene has three ongoing clinical trials of onvansertib: A Phase 2 trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with mCRPC who are showing signs of early progressive disease (rise in PSA but minimally symptomatic or asymptomatic) while currently receiving Zytiga® (NCT03414034); a Phase 1b/2 Study of onvansertib in combination with FOLFIRI and Avastin® for second-line treatment in patients with mCRC with a KRAS mutation (NCT03829410); and a Phase 1b/2 clinical trial of onvansertib in combination with low-dose cytarabine or decitabine in patients with relapsed or refractory AML (NCT03303339). Onvansertib has been granted orphan drug designation by the FDA in the U.S. and by the EC in the European Union for the treatment of patients with AML.

Trovagene licensed onvansertib (also known as NMS-1286937 and PCM-075) from Nerviano Medical Sciences (NMS), the largest oncology-focused research and development company in Italy, and a leader in protein kinase drug development. NMS has an excellent track record of licensing innovative drugs to pharma/biotech companies, including Array (recently acquired by Pfizer), Ignyta (acquired by Roche) and Genentech.

About Trovagene, Inc.

Trovagene is a clinical-stage, Precision Cancer Medicine™ oncology therapeutics company developing drugs that target cell division (mitosis), for the treatment of various cancers 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, 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.

Trovagene Contact:
Vicki Kelemen
VP, Clinical Development and Investor Relations
858-952-7652
vkelemen@trovagene.com