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): **September 19, 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 September 19, 2019, Trovagene, Inc. issued a press release announcing the successful completion of its Phase 1b trial of onvansertib in combination with standard-of-care chemotherapy in acute myeloid leukemia (AML) and initiation of patient enrollment in Phase 2. 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 September 19, 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: September 19, 2019

TROVAGENE, INC.

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

Trovagene Announces Successful Completion of Phase 1b Trial of Onvansertib in Acute Myeloid Leukemia (AML) and Initiation of Patient Enrollment in Phase 2

- ***Phase 1b dose escalation clinical trial confirmed safety, preliminary efficacy and identified the recommended phase 2 dose of onvansertib***
- ***Complete response (CR + CRi) achieved in 5 of 21 patients treated with onvansertib in combination with decitabine***
- ***Phase 2 will treat 32 patients with onvansertib + decitabine; eligible patients will have relapsed after receiving up to one prior therapy including first-line treatment with venetoclax***

SAN DIEGO (September 19, 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 successful completion of its Phase 1b trial of onvansertib in combination with standard-of-care chemotherapy in acute myeloid leukemia (AML) and initiation of patient enrollment in Phase 2.

The Phase 1b dose-escalation trial confirmed that onvansertib in combination with standard-of-care chemotherapy is safe and well tolerated. Additionally, the primary efficacy endpoint of objective response (CR + CRi) was achieved in 5 of 21 patients treated with onvansertib + decitabine, indicating anti-leukemic activity in this difficult-to-treat relapsed/refractory AML population. Importantly, 30% of patients treated were biomarker positive, which was associated with an increase in response to treatment as measured by decreases in bone marrow blasts and the rate of complete response.

Data from the Phase 1b AML trial will be featured in an oral presentation at the European Society for Medical Oncology (ESMO) in Barcelona, Spain on Saturday, September 28th and will be available for download from the Scientific Presentations page on the Trovagene website at https://trovageneoncology.com/scientific-presentations/.

“Initiation of our Phase 2 trial in AML is a significant step forward in the development of onvansertib for the treatment of AML,” said Thomas Adams, PhD, Chief Executive Officer and Chairman of Trovagene. “We are very pleased by the safety and clinical activity observed with onvansertib in combination with standard-of-care chemotherapy in patients with relapsed or refractory AML, where there remains a significant need for new effective treatment options. Our Phase 2 trial will focus on patients who are showing resistance to first-line treatment, including venetoclax. Our preclinical data showed anti-tumor activity of onvansertib in a venetoclax-resistant AML xenograft model, suggesting its potential to provide a new and effective treatment option for these patients.”

The Phase 2 AML trial will enroll 32 patients who are either treatment naïve and not candidates for induction therapy or who have relapsed following up to one prior regimen. Patients will receive onvansertib on days 1 through 5 in combination with decitabine in a 21-28 day cycle.

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), colorectal cancer and triple-negative breast cancer (TNBC), as well as other types of cancer.

In addition to the Phase 1b/2 AML trial, Trovagene has two other ongoing trials: a Phase 2 trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with mCRPC (NCT03414034) who are showing signs of early progressive disease (rise in PSA but minimally symptomatic or asymptomatic) while currently receiving Zytiga®; and a Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin® for second-line treatment in patients with mCRC with a KRAS mutation (NCT03829410).

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 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.

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