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): **August 26, 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 August 26, 2019, Trovagene, Inc. issued a press release announcing the presentation of positive clinical data from its ongoing Phase 2 clinical trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone, an androgen-receptor signaling (ARS) inhibitor, in metastatic Castration-Resistant Prostate Cancer (mCRPC), at the 20th Asia-Pacific Prostate Cancer Conference in Melbourne, Australia. 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 August 26, 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: August 26, 2019

TROVAGENE, INC.

By: /s/ Thomas Adams

Thomas Adams

Chief Executive Officer

Trovagene Presents Positive Clinical Data from Ongoing Phase 2 Study of Onvansertib in Metastatic Castration-Resistant Prostate Cancer (mCRPC)

- ***Trial leads to discovery that onvansertib stops rise in PSA in patients with treatment-resistant, highly-aggressive and difficult-to-treat androgen-receptor variant 7 (AR-V7) tumors***
- ***Data demonstrates efficacy of onvansertib in patients showing early signs of resistance to androgen receptor signaling (ARS) inhibitor, Zytiga®***
- ***Addition of onvansertib appears to extend the duration of response to ARS inhibitor therapy in this incurable and lethal cancer***

SAN DIEGO (August 26, 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 prostate, colorectal and leukemia, today announced the presentation of positive clinical data from its ongoing Phase 2 clinical trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone, an androgen-receptor signaling (ARS) inhibitor, in metastatic Castration-Resistant Prostate Cancer (mCRPC), at the 20th Asia-Pacific Prostate Cancer Conference in Melbourne, Australia. These data demonstrate the efficacy of onvansertib in patients showing resistance to the ARS inhibitor, Zytiga® (Johnson & Johnson), including those with the highly-aggressive and difficult-to-treat androgen receptor variant 7 (AR-V7) tumor.

“We have discovered that adding onvansertib to daily ARS inhibitor therapy changes the trajectory of resistance in patients harboring AR-V7, as demonstrated by the immediate decrease in serum PSA levels in patients showing initial signs of resistance to Zytiga®,” said Mark Erlander, PhD, Chief Scientific Officer of Trovagene. “The inhibition of the PLK1 enzyme by onvansertib appears to enhance the efficacy of Zytiga® by repressing the ARS pathway, which is consistent with preclinical data.”

In the ongoing Phase 2 clinical trial of onvansertib, a first-in-class, oral and highly-selective PLK1 inhibitor, patients are being tested with a simple blood test to assess whether they are positive for AR-V7. In all four patients who tested positive for AR-V7, thus far, an immediate decrease in their serum PSA levels was observed. To-date, two of these patients have achieved the primary efficacy endpoint of disease control. Importantly, while on Zytiga® alone the PSA level for one of the AR-V7 positive patients had a greater than five-fold rise in the two months prior to enrollment and treatment in the trial. Once onvansertib was added to Zytiga®, the patient’s PSA level stopped rising and immediately decreased; the patient remains on treatment.

Additionally, since presenting early data at the American Association for Cancer Research in April, a second arm (Arm B) with a two-week dosing schedule and 50% greater drug exposure to onvansertib over the treatment course, was added to the trial. Preliminary efficacy with PSA stabilization or reduction was observed in the initial three patients enrolled, suggesting that a shorter dosing schedule may maximize response to treatment. Importantly, no unexpected, off-target toxicities have been reported in patients treated to-date.

mCRPC is an incurable and lethal cancer. Nearly all patients with prostate cancer will progress to castration resistance, indicated by increasing serum PSA levels despite castrate levels of testosterone and progress to metastases. 10% to 20% of prostate cancers progress to castration resistant prostate cancer (CRPC) within 5 years of diagnosis, and 84% of newly diagnosed CRPC have metastases. The median survival of patients following diagnosis of castration resistance ranges between 15 and 36 months. The standard-of-care first-line treatment are ARS inhibitors, Zytiga® (Johnson & Johnson) or Xtandi® (Pfizer); however, resistance to these drugs

typically develops within 9 to 15 months of initiating treatment. Additionally, up to 30% of patients have the highly-aggressive and ARS-resistant AR-V7. These patients have a shorter progression-free survival (PFS), overall survival (OS) and a poor prognosis. Current treatment for these patients is limited to toxic chemotherapy and there are no effective targeted therapies available.

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 an ongoing Phase 2 clinical 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®. The trial was accepted by the NLM and is now posted to www.clinicaltrials.gov, with a NCT number of NCT03414034.

Trovagene has an ongoing Phase 1b/2 Study of onvansertib in combination with FOLFIRI and Avastin® for second-line treatment in patients with mCRC with a KRAS mutation. The trial was accepted by the NLM and is now posted to www.clinicaltrials.gov, with a NCT number of NCT03829410. The trial is being conducted at three prestigious cancer centers: USC Norris Comprehensive Cancer Center, Hoag Cancer Center and The Mayo Clinic.

Trovagene has an ongoing Phase 1b/2 clinical trial of onvansertib in combination with low-dose cytarabine or decitabine in patients with relapsed or refractory AML that was accepted by the National Library of Medicine (NLM) and is now posted to www.clinicaltrials.gov, with a NCT number of 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 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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