

**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): **July 22, 2019**

Trovagene, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-35558
(Commission File
Number)

27-2004382
(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:

<u>Title of each class:</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered:</u>
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:

- 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 July 22, 2019, Trovogene, Inc. issued a press release announcing the acceptance of three abstracts for presentation at the upcoming European Society for Medical Oncology (ESMO) conference to be held from Sept. 27 to Oct. 1, 2019, in Barcelona. 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 Trovogene, Inc. dated July 22, 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: July 22, 2019

TROVAGENE, INC.

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



ESMO Accepts Trovogene AML Clinical Trial Abstract for Oral Presentation

- *Acute Myeloid Leukemia (AML) clinical trial data to be presented in an oral presentation*
- *Metastatic Colorectal Cancer (mCRC) clinical trial data and triple-negative breast cancer (TNBC) preclinical data to be presented in two poster presentations*

SAN DIEGO — July 22, 2019 — Trovogene, Inc. (Nasdaq: TROV), a clinical-stage, Precision Cancer Medicine™ oncology therapeutics company, today announced the acceptance of three abstracts for presentation at the upcoming European Society for Medical Oncology (ESMO) conference to be held from Sept. 27 to Oct. 1, 2019, in Barcelona.

“Having our AML clinical trial abstract chosen for an oral presentation by the ESMO Scientific Committee, indicates that we have achieved, with this trial, a level of interest in onvansertib that warrants a high profile venue for communicating its potential as a novel, first-in-class, PLK1 inhibitor to address this difficult-to-treat cancer,” said Tom Adams, PhD, Chief Executive Officer and Chairman of Trovogene. “Additionally, onvansertib’s extension into solid tumor cancers will be showcased in a poster presentation providing an overview of our Phase 1b/2 trial in KRAS-mutated mCRC. As we continue evaluating onvansertib in other indications, we are also pleased to have a poster that will present preclinical data showing synergy in combination with paclitaxel in TNBC. ESMO is the ideal forum at which to present these data as this conference gathers leading experts across the oncology field.”

The abstract accepted for an oral presentation (Abstract #2411), **“Polo-like Kinase Inhibitor, Onvansertib, in Combination with Low-Dose Cytarabine or Decitabine in Patients with Relapsed/Refractory Acute Myeloid Leukemia in Phase 1b,”** will be presented by Amer Zeidan, MBBS, MHS, Yale University, and will feature safety and preliminary efficacy data, including patients who achieved a complete response, as well as biomarker data and correlation with treatment response.

In addition, there will be two poster presentations at the conference. The first poster presentation (Abstract #3695), **“A Phase 1b/2 Study of Onvansertib (PCM-075) in Combination with FOLFIRI and Bevacizumab for Second Line Treatment of Metastatic Colorectal Cancer in Patients with a KRAS Mutation,”** will be presented by Heinz-Josef Lenz, MD, USC Norris Comprehensive Cancer Center, and will feature preliminary safety and efficacy data, as well as biomarker data showing changes in the KRAS mutation burden in patients treated in the initial dose level cohort.

Trovogene Inc. | 11055 Flintkote Avenue | San Diego | CA 92121 | Tel.: USA [+1] 888-391-7992

The second poster presentation (Abstract #5818), **“Polo-like Kinase 1 Inhibitor Onvansertib Synergizes with Paclitaxel in Breast Cancer Carrying p53 Mutation,”** will be presented by Antonio Giordano, MD, PhD, Medical University of South Carolina, and will feature preclinical *in vivo* data demonstrating synergy of onvansertib in combination with paclitaxel in xenograft models of triple-negative breast cancer carrying the p53 mutation.

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. Trovogene 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. Trovogene 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.

Trovogene 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.

Trovogene 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.

Trovogene 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 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, 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.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 Trovogene'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 Trovogene does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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