
**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): **October 2, 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:

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:

- 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.

Data Presented at ESMO Provides Rationale for Clinical Trial of Onvansertib in Subset of Patients with Highly-Aggressive Triple Negative Breast Cancer (TNBC)

- *Significant tumor regression observed with onvansertib in combination with standard-of-care paclitaxel in models of p53-mutated TNBC*
- *Onvansertib preclinical data provides rationale for clinical trial targeting the 80% of TNBC that harbors the p53 mutation*
- *Combination has potential to address critical medical need to provide targeted treatment option to overcome resistance to paclitaxel as single agent therapy in TNBC*

SAN DIEGO (October 2, 2019) – **Trovogene, 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 breast, prostate, colorectal and leukemia, today announced the presentation of preclinical data demonstrating significant tumor regression with the combination of onvansertib and paclitaxel, versus either agent alone, in models of triple-negative breast cancer (TNBC).

The data was featured in a poster presentation at the European Society for Medical Oncology (ESMO) Annual Congress on Sunday, September 29th, 2019.

“The development of new options to treat TNBC that is resistant to standard-of-care chemotherapy can address a critical unmet clinical need,” said Antonio Giordano, MD, PhD, medical oncologist at Medical University of South Carolina (MUSC). “We value our collaboration with Trovogene, and we believe that our preclinical data confirms the potential therapeutic benefit of onvansertib and warrants further evaluation. Planning for the initiation of a clinical trial targeting TNBC patients with the highly-aggressive p53 mutation is currently underway at MUSC.”

TNBC is an aggressive form of the disease accounting for 12 to 18% of breast cancers. Although chemotherapy can be effective as standard-of-care, many patients become resistant to treatment. The TP53 gene is mutated in approximately 80% of TNBC and the mutation is considered a target marker. TNBC is defined by the absence of estrogen and progesterone receptors and the absence of HER2 overexpression. These cancers represent a heterogeneous breast cancer subtype with a poor prognosis. Few systemic treatment options exist besides the use of chemotherapy. Currently, there are no approved targeted therapies to treat TNBC.

Presentation Highlights

Background:

- Somatic mutation in TP53 gene (mutp53) is a strong prognostic marker in breast cancer
- Triple negative breast cancer (TNBC) is characterized by up to 80% mutp53 and the greatest overall genomic instability among subtypes
- Polo-like kinase 1 (PLK1) regulates progression of cells through the G2 phase of the cell cycle

- Hypothesis that mutp53 in the context of breast cancer can predict synergy to paclitaxel plus onvansertib, an orally available highly selective PLK1 inhibitor

Significant Clinical Need for New Targeted Treatment Option (Onvansertib + Paclitaxel):

- Cell lines undergo G2/M cell-cycle arrest following PLK1 (onvansertib) inhibition
- Paclitaxel synergizes with onvansertib (the activity of the two drugs together is greater than that of each drug alone) and induces apoptosis (death) of cancer cells
- Currently, treatment options are limited to chemotherapy and there is a significant medical need to develop a targeted therapeutic option for the treatment of breast cancer patients with TP53 mutation
- A clinical study to assess the safety and preliminary efficacy of the combination of onvansertib and paclitaxel as a potential new targeted treatment option in TNBC is warranted

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 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.

Trovogene 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 Trovogene, Inc.

Trovogene 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. Trovogene 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. Trovogene plans to continue to vertically integrate its tumor genomics technology with the development of targeted cancer therapeutics. For more information, please visit <https://www.trovogeneoncology.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 Trovogene's expectations, strategy, plans or intentions. These forward-looking statements are based on Trovogene'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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