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**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): **April 28, 2020**

**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:**

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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 April 28, 2020, Trovogene, Inc. issued a press release announcing new positive results from its ongoing Phase 1b/2 clinical trial of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for second-line treatment of patients with KRAS-mutated metastatic colorectal cancer (mCRC). 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 April 28, 2020](#)

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: April 28, 2020

TROVAGENE, INC.

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

## Onvansertib Trial in KRAS-Mutated Colorectal Cancer Demonstrates Consistent Tumor Regression Across KRAS Mutation Subtypes and Durable Response

- *Ongoing Phase 1b/2 trial has enrolled 12 patients with 88% response in 7 of 8 evaluable patients; to-date 3 patients with a partial response (PR); 4 patients with stable disease (SD)*
- *Data show median progression-free survival (PFS) of at least 6.5 months with 6 patients continuing on treatment to-date; one patient has gone on to have successful curative surgery*
- *Changes in KRAS mutation blood levels is the biomarker used in this trial; decreases to non-detectable in cycle one of treatment is predictive of future tumor regression and response*

**SAN DIEGO (April 28, 2020) – Trovogene, Inc. (Nasdaq: TROV)**, a clinical-stage, oncology therapeutics company developing drugs to treat cancers with the greatest medical need for new treatment options, including colorectal cancer, prostate cancer and leukemia, today announced new positive results from its ongoing Phase 1b/2 clinical trial of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for second-line treatment of patients with KRAS-mutated metastatic colorectal cancer (mCRC). The data were featured in a virtual oral presentation, delivered by Dr. Afsaneh Barzi, at the American Association for Cancer Research (AACR) conference on Monday, April 27<sup>th</sup>, 2020.

There is a significant, unmet medical need to develop a safe and effective second-line treatment option for patients with KRAS-mutated mCRC. Currently available treatments have limited efficacy with only a 4% response rate and a median of 5.5 months PFS. Other compounds currently in clinical development that target KRAS-mutated cancers have shown minimal activity in mCRC.

“We are encouraged by the level of activity that we are observing with the combination of onvansertib and standard-of-care FOLFIRI and bevacizumab in our patients with KRAS-mutated colorectal cancer,” said Dr. Afsaneh Barzi, principal investigator, who led the trial as an associate professor of clinical medicine at Keck School of Medicine of USC and medical oncologist at USC Norris Comprehensive Cancer Center. “So far we are observing what we had hoped for in this trial – lack of toxicity and positive signs of efficacy. We remain optimistic because we are observing anti-tumor effects of onvansertib, which could present the opportunity for a new treatment designed to attack KRAS-mutant tumors and act synergistically with standard-of-care chemotherapy.”

### Highlights of AACR Presentation - Onvansertib in KRAS-Mutated mCRC Trial

- In the Phase 1b dose escalation, the 1st two dose levels (onvansertib 12 mg/m<sup>2</sup> and 15 mg/m<sup>2</sup>) have been cleared for safety; the 3rd dose level (onvansertib 18 mg/m<sup>2</sup>) is enrolling; the maximum tolerated dose has not been reached to-date
- As of the data cut-off date, clinical response was observed in 7 (88%) of the 8 evaluable patients:
  - o 3 patients had partial response (PR), 4 patients had stable disease (SD)
  - o 1 patient proceeded to have successful curative surgery

- o Progression-free survival (PFS) is 6.5 months to date, with 6 patients remaining on treatment
- Decreases in plasma KRAS mutation level has been demonstrated to be an early marker for therapeutic response:
  - o Onvansertib effectively targets predominant KRAS mutants associated with CRC
  - o 7 of the 8 patients had a KRAS mutation detected by ctDNA analysis at baseline (ddPCR and NGS)
  - o Changes in KRAS mutant during cycle 1 of treatment were highly predictive of tumor regression:
    - § 5 patients had a decrease in KRAS mutant to non-detectable level in cycle 1 (28 days) and subsequent tumor regression at 8 weeks
    - § 2 patients had detectable KRAS mutant at end of cycle 1 and showed tumor growth at 8 weeks
- The Phase 2 continuation trial will further assess the safety and efficacy of onvansertib at the recommended Phase 2 dose (RP2D) in combination with FOLFIRI + bevacizumab, as well as the value of KRAS liquid biopsy to predict treatment response

### **About the Phase 1b/2 Clinical Trial of Onvansertib in KRAS-Mutated mCRC**

The ongoing trial, *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* (NCT03829410) is evaluating the safety and efficacy of onvansertib in combination with standard-of-care FOLFIRI and Avastin® (bevacizumab). Up to 44 patients, with a confirmed KRAS mutation, metastatic and unresectable disease, who have failed or are intolerant of treatment with FOLFOX (fluoropyrimidine and oxaliplatin) with or without Avastin® (bevacizumab), will be enrolled. The trial is being conducted at two prestigious cancer centers: USC Norris Comprehensive Cancer Center and the Mayo Clinic Cancer Center.

### **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.

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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 2 clinical trial of onvansertib in combination with decitabine in patients with relapsed or refractory AML (NCT03303339).

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 biotechnology company with the singular mission of developing new treatment options for cancer patients in indications with the greatest medical need. Our goal is to overcome resistance, improve response to treatment and increase overall survival. We are developing onvansertib, a first-in-class, third-generation Polo-like Kinase 1 (PLK1) inhibitor, in combination with standard-of-care chemotherapy and targeted therapeutics. Our clinical development programs incorporate tumor genomics and biomarker technology to enable assessment of patient response to treatment. 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; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase our costs and expenses; 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.

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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, 2019, 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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