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): June 21, 2018

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)

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 June 21, 2018, Trovagene, Inc. issued a press release announcing they have received Institutional Review Board (IRB) approval from Dana-Farber/Harvard Cancer Center and its Phase 2 clinical trial of PCM-075 in combination with Zytiga® (abiraterone acetate) and prednisone in metastatic Castration-Resistant Prostate Cancer (mCRPC) is officially activated and recruiting patients. 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 June 21, 2018

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: June 21, 2018

TROVAGENE, INC.

By: /s/ William J. Welch
William J. Welch
President and Chief Executive Officer

Trovagene Announces the Start of Recruitment and Enrollment for Phase 2 Clinical Trial of PCM-075 in Combination with Zytiga® in Patients with mCRPC

Beth Israel Deaconess Medical Center, Dana-Farber Cancer Institute and Massachusetts General Hospital officially activated and recruiting patients for Phase 2 open-label trial of PCM-075 and abiraterone acetate (Zytiga®) in metastatic Castration-Resistant Prostate Cancer (mCRPC)

SAN DIEGO, CA – June 21, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, developing targeted therapeutics for the treatment of hematologic and solid tumor cancers, today announced they have received Institutional Review Board (IRB) approval from Dana-Farber/Harvard Cancer Center and its Phase 2 clinical trial of PCM-075 in combination with Zytiga® (abiraterone acetate) and prednisone in metastatic Castration-Resistant Prostate Cancer (mCRPC) is officially activated and recruiting patients. The trial is being conducted by Beth Israel Deaconess Medical Center (BIDMC), Dana-Farber Cancer Institute (Dana-Farber), and Massachusetts General Hospital Cancer Center (MGH). David Einstein, MD, Genitourinary Oncology Program at BIDMC, is the principal investigator for the trial.

In this multi-center, open-label, Phase 2 trial, PCM-075 in combination with the standard dose of Zytiga® (abiraterone acetate) and prednisone, all administered orally, will be evaluated for safety and efficacy. The Phase 2 clinical trial will enroll up to 45 patients, with mCRPC, showing signs of disease progression demonstrated by two rising PSA values separated by at least one week, while on abiraterone acetate and prednisone therapy. The primary efficacy endpoint is the proportion of patients achieving disease control after 12 weeks of study treatment, as defined by lack of prostate specific antigen (PSA) progression in patients who are showing signs of early progressive disease (rise in PSA but minimally symptomatic or asymptomatic) while currently receiving abiraterone acetate and prednisone.

“Prostate cancer will kill an estimated 29,430 men in the United States this year. It is clear that resistance to standard therapies continues to be an urgent problem for our patients. Pre-clinical work has identified polo-like kinase 1 as a drug target meriting study in combination with abiraterone,” said Dr. Einstein.

“We are excited to be working with the Dana-Farber/Harvard Cancer Center and look forward to evaluating the impact of PCM-075 in combination with abiraterone acetate in patients with mCRPC,” said Bill Welch, Chief Executive Officer of Trovagene.

About Castration-Resistant Prostate Cancer (CRPC)

Castration-Resistant Prostate Cancer (CRPC) is defined by disease progression despite androgen-deprivation therapy (ADT) and may present as one or any combination of a continuous rise in serum levels of prostate-specific antigen (PSA), progression of pre-existing

disease, or appearance of new metastases. Prognosis is associated with several factors, including performance status, presence of bone pain, extent of disease on bone scan, and serum levels of alkaline phosphatase. Bone metastases occur in 90% of men with CPRC and can produce significant morbidity, including pain, pathologic fractures, spinal cord compression, and bone marrow failure. Paraneoplastic effects are also common, including anemia, weight loss, fatigue, hypercoagulability, and increased susceptibility to infection. Institution of treatment and the choice of systemic or local therapy depend on a number of factors.

About PCM-075

PCM-075 is a highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK 1) enzyme, which is over-expressed in multiple hematologic and solid tumor cancers. PCM-075 only targets PLK1 isoform (not PLK2 or PLK3), is oral, has a 24-hour drug half-life with reversible on-target hematologic toxicities. A Phase 1 open-label, dose escalation safety study of PCM-075 has been completed in patients with advanced metastatic solid tumor cancers and published in 2017 in *Investigational New Drugs*. The maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) in this trial was 24 mg/m^2.

PCM-075 has demonstrated synergy in preclinical studies with over 10 chemotherapeutic and target agents used in hematologic and solid tumor cancers, including abiraterone acetate (Zytiga®), FLT3 and HDAC inhibitors, taxanes, and cytotoxins. Trovagene believes the combination of its targeted PLK1 inhibitor, PCM-075, with other compounds has the potential for improved clinical efficacy in Acute Myeloid Leukemia (AML), metastatic Castration-Resistant Prostate Cancer (mCRPC), Non-Hodgkin Lymphoma (NHL), Triple Negative Breast Cancer (TNBC), as well as other hematologic and solid tumor cancers.

Trovagene has a Phase 2 trial in metastatic Castration-Resistant Prostate Cancer that was accepted by the National Library of Medicine (NLM) and is now publicly viewable on www.clinicaltrials.gov. The NCT number assigned by clinicaltrials.gov for this study is NCT03414034.

About Trovagene, Inc.

Trovagene is a clinical-stage, oncology therapeutics company. The Company's primary focus is to develop oncology therapeutics for the treatment of hematologic and solid tumor cancers for improved cancer care, utilizing its technology in tumor genomics. 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.trovagene.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, or that Trovagene’s strategy to design its liquid biopsy tests to report on clinically actionable cancer genes will ultimately be successful or result in better reimbursement outcomes. 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, 2017, 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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