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 9, 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 July 9, 2018, Trovagene, Inc. issued a press release providing an update on key value-creating milestones for the second half of 2018 and a review of its year-to-date achievements. 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 July 9, 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: July 10, 2018

TROVAGENE, INC.

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

Trovagene Presents Outlook for Second Half of 2018

SAN DIEGO, July 9, 2018 /PRNewswire/ — Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, developing targeted therapeutics for the treatment of hematologic and solid tumor cancers, today provided an update on key value-creating milestones for the second half of 2018 and a review of its year-to-date achievements.

“We continue to focus on advancing our two active clinical trials with PCM-075; a Phase 1b/2 trial in patients with Acute Myeloid Leukemia (AML) and a Phase 2 trial in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC),” said Tom Adams, Chairman of the Board and Interim Chief Executive Officer of Trovagene. “We believe PCM-075 has the potential to address a critical need for new treatment options for patients across a variety of leukemias/lymphomas and solid tumor cancers.”

“As a team, we achieved a number of key milestones in the first half of 2018 and we continue to execute on our business plan and to advancing our clinical development program in the second half of 2018. We are encouraged by the high level of interest from outside parties and we are evaluating strategic development partnerships for our drug asset outside the U.S.”

Looking ahead to the second half of 2018, the Company’s Board of Directors is undertaking a search for a new CEO, who has the relevant therapeutic and drug development experience to lead Trovagene into its next stage.

Anticipated Second Half 2018 Milestones

Trovagene anticipates achieving the following milestones during the second half of 2018:

Clinical Milestones for PCM-075

Phase 1b/2 trial of PCM-075 in Combination with Either Low-Dose Cytarabine (LDAC) or Decitabine for the Treatment of Acute Myeloid Leukemia (AML)

- Complete Phase 1b dose escalation cohorts and identify the recommended Phase 2 dose (RP2D) for the Phase 2 continuation trial (dependent upon the number of dose escalation cohorts required to reach the maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) of PCM-075)

- Provide topline preliminary safety and efficacy data on the combination of PCM-075 + LDAC and the combination of PCM-075 + decitabine in patients treated through the end of 2018
- Present data from the AML trial at the 60th annual American Society of Hematology (ASH) conference
- Initiate the Phase 2 segment of the AML trial, which will enroll 32 patients for continued evaluation of safety and preliminary efficacy of PCM-075 in combination with either LDAC or decitabine (provided the RP2D has been determined in Phase 1b)

Phase 2 trial of PCM-075 in Combination with Abiraterone Acetate (Zytiga®) and Prednisone for the Treatment of Metastatic Castration-Resistant Prostate Cancer (mCRPC)

- Complete enrollment and cycle 1 of treatment of the 3 safety lead-in patients with PCM-075 at 24 mg/m^2 in combination with abiraterone acetate (Zytiga®) and prednisone
- Evaluate the three lead-in patients in the mCRPC trial for safety
- Provide topline preliminary safety and efficacy data of PCM-075 in combination with abiraterone acetate (Zytiga®) and prednisone in patients treated through the end of 2018

First Half 2018 Achievements and Highlights

Trovagene achieved important clinical milestones during the first half of 2018, highlighted by the following accomplishments:

- Announced Preliminary Clinical Data from First Dosing Cohort Demonstrating Durable Treatment Effect of PCM-075 in Combination with Cytarabine or Decitabine in Patients with Relapsed or Refractory AMLOn June 27, 2018, Trovagene announced preliminary clinical data from the first dosing cohort showing a treatment effect with PCM-075 in combination with low-dose cytarabine (LDAC) or decitabine, as measured by decreases in leukemic cells in both peripheral blood and bone marrow in patients in its ongoing Phase 1b/2 trial in relapsed or refractory Acute Myeloid Leukemia (AML). Both blood and bone marrow samples were obtained from patients with relapsed or refractory AML enrolled in the Phase 1b/2 trial prior to, and at timepoints following administration of PCM-075, in combination with cytarabine or decitabine. Among the 6 patients evaluated, no dose-limiting toxicities (DLTs) were observed that would prohibit further escalation of the PCM-075 dosing. Three patients exhibited substantial reductions in the percentage of both circulating leukemic cells within the blood and leukemic

cells within the bone marrow. Two of these three patients continued on treatment in the second cycle and further decreases in circulating leukemic cells in the blood and within the bone marrow were observed. One patient had a decrease in his bone marrow blasts from 96% to 40% at the end of cycle 2 and has continued on treatment in cycle 3.

- Announced the Start of Recruitment and Enrollment for Phase 2 Clinical Trial of PCM-075 in Combination with Zytiga® in Patients with mCRPC On June 21, 2018, Trovagene 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.
- Announced Completion of First Dosing Cohort of Patients Treated with PCM-075 in Combination with Decitabine in Ongoing Phase 1b/2 AML trialOn June 15, 2018, Trovagene announced completion of the first dose cohort of PCM-075, a highly-selective Polo-like Kinase 1 (PLK1) Inhibitor, in combination with decitabine, in its Phase 1b/2 clinical trial in patients with Acute Myeloid Leukemia (AML). Three patients were treated with PCM-075 at 12 mg/m2, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with decitabine. The combination of PCM-075 and decitabine was well tolerated in all patients. The independent Safety Review Committee (SRC) has recommended escalating to the second dose cohort of three patients at 18 mg/m^2 of PCM-075 (approximately a 50% increase) in combination with decitabine.
- Announced Completion of First Dosing Cohort of Patients in Ongoing Phase 1b/2 AML trial of PCM-075 in Acute Myeloid LeukemiaOn May 17, 2018, Trovagene announced the completion of the first dose cohort in its Phase 1b/2 clinical trial of PCM-075, a highly-selective Polo-like Kinase 1 (PLK1) Inhibitor, in combination with LDAC, in Acute Myeloid Leukemia (AML). Three patients were treated with PCM-075 at 12 mg/m^2, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with LDAC. Patients eligible for Phase 1bhave relapsed or refractory disease and may have received as many as three prior regimens for treatment of their AML. The combination of PCM-075 and LDAC was well tolerated in all patients. The independent Safety Review Committee (SRC) has recommended escalating to the second dose cohort of three patients at PCM-075 at 18 mg/m^2 (approximately a 50% increase) in combination with LDAC.

- Announced Presentation of Data at AACR Meeting 2018 on Pharmacodynamic and Tumor Biomarkers During Treatment with PCM-075 and Low-Dose CytarabineOn April 17, 2018, Trovagene announced the presentation of pharmacodynamic and biomarker data from the first patient to complete a safety treatment cycle in its Phase 1b/2 clinical trial of PCM-075, a highly-selective Polo-like Kinase 1 (PLK1) Inhibitor, in Acute Myeloid Leukemia (AML). The poster entitled Pharmacodynamic and Tumor Biomarker Analysis of a PLK1 Inhibitor, PCM-075, in a Phase 1b/2 Trial for Acute Myeloid Leukemia presents the methodology developed to track dynamic changes in blood leukemic cells, genomic alterations and PLK1 inhibition in AML patients treated with PCM-075 in combination with LDAC.
- Announced Presentation of data at AACR Meeting 2018 Showing Synergy of PCM-075 in Combination with FLT3 Inhibitors in Acute Myeloid Leukemia (AML) On April 16, 2018, Trovagene announced the presentation of data showing that PCM-075 exhibits synergistic activity when combined with FLT3 inhibitors in a human xenograft acute myeloid leukemia (AML) model, at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, IL. The poster entitled Selective Polo-like Kinase 1 (PLK1) Inhibitor PCM-075 is Highly Active Alone and Shows Synergy When Combined with FLT3 Inhibitors in Models of Acute Myeloid Leukemia (AML) presents data demonstrating that PCM-075 in combination with quizartinib (Daiichi-Sankyo) resulted in 97.3% tumor growth inhibition (TGI), compared to 77.9% with quizartinib and 80.2% with PCM-075 as monotherapy.
- Announced First Patient Successfully Completes Cycle 1 of Treatment with PCM-075 in Combination with Low-Dose Cytarabine (LDAC) in AML TrialOn March 5, 2018, Trovagene announced that the initial patient successfully completed the first cycle 1 of treatment in its Phase 1b/2 multicenter trial of PCM-075 in combination with low-dose cytarabine (LDAC) in patients with Acute Myeloid Leukemia (AML). The patient tolerated the combination well and correlative analyses of blood samples, taken at specified time points, also indicated activity on leukemic blood cells. A significant decrease in the percentage of blood leukemic cells was observed within 24 hours of administering PCM-075 + LDAC. By day 15, within the treatment cycle, the greatest effect was observed with blood leukemic cells showing a decrease from greater than 40% to less than 5%. Additionally, the same tumor DNA mutations (ASXL1 and SRSF2) were detected in the bone marrow and blood, indicating consistency across samples and validity of the analyses. Both DNA mutations appeared to quantitatively track with the decrease in blood leukemic cells.

- Announced Presentation of Data Showing Synergy of PCM-075 in Combination with Zytiga® (abiraterone acetate) in Castration-Resistant Prostate Cancer Model at 2018 Genitourinary Cancers Symposium On February 9, 2018, Trovagene announced that preclinical data demonstrating the synergy of PCM-075, its highly-selective Polo-like kinase 1 (PLK1) Inhibitor, in combination with abiraterone acetate (Zytiga® – Johnson & Johnson), will be featured as a Poster Presentation at the 2018 Genitourinary Cancers Symposium on February 9th, from 12:15 – 1:45 PMand 6:00 – 7:00 PM PST, in San Francisco, California. The poster entitled Combination of Selective Polo-like Kinase 1 (PLK1) Inhibitor PCM-075 with Abiraterone in Prostate Cancer and Non-Androgen-Driven Cancer Models showcases data from Dr. Michael Yaffe's lab at the Koch Institute for Integrative Cancer Research at Massachusetts Institute of Technology and will be presented by Dr. Jesse Patterson.

The underlying mechanism of synergy was further examined by performing gene-expression comparison across more than 30 different synergistic and non-synergistic cell lines across multiple tumor types. From this analysis, multiple hypothesis-generating mechanisms were identified, one of which was the retinoic acid pathway, which when activated is predictive of synergy.

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. Separate studies with other PLK inhibitors have shown that inhibition of polo-like-kinases can lead to tumor cell death, including a Phase 2 study in Acute Myeloid Leukemia (AML) where response rates up to 31% were observed when used in conjunction with a standard therapy for AML (low-dose cytarabine-LDAC) versus treatment with LDAC alone with a 13.3% response rate. 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 Investigational New Drugs. The maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) in this trial was 24 mg/m^2. Trovagene has an ongoing Phase 1b/2 clinical trial with PCM-075 in AML 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 NCT03303339. PCM-075 has been granted Orphan Drug Designation by the FDA for the treatment of patients with AML. Trovagene is enrolling a Phase 2 trial of PCM-075 in combination with ZytigaÒ (abiraterone acetate) and prednisone in metastatic Castration- Resistant Prostate Cancer that was accepted by the National Library of Medicine (NLM) and is now publicly viewable on www.clnincaltrials.gov. The NCT number assigned by clinicaltrials.gov for this study is NCT03414034.

PCM-075 only targets the PLK1 isoform (not PLK2 or PLK3), is orally available, has a 24-hour drug half-life with reversible on-target hematologic toxicities. Trovagene believes that targeting only PLK1 with reversible on-target activity and an improved dose/scheduling protocol can significantly improve on the long-term outcome observed in previous studies with a PLK inhibitor in AML.

PCM-075 has demonstrated synergy in preclinical studies with over 10 chemotherapeutic and target agents used in hematologic and solid tumor cancers, including 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.

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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