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): November 7, 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 2.02 Results of Operations and Financial Condition

On November 7, 2018, Trovagene, Inc. issued a press release announcing company highlights and financial results for the third quarter ended September 30, 2018. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 Press Release of Trovagene, Inc. dated November 7, 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: November 9, 2018

TROVAGENE, INC.

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

Trovagene Announces Third Quarter 2018 Highlights and Financial Results

SAN DIEGO, CA – November 7, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, using a precision medicine approach to develop drugs that target cell division (mitosis) for the treatment of leukemias, lymphomas and solid tumor cancers, today announced company highlights and financial results for the third quarter ended September 30, 2018. The Company is issuing this press release in lieu of conducting a conference call.

“We are pleased with the progress we are making in the clinical development of onvansertib in the cancers and indications where there is a significant need to bring new treatment options to physicians and their patients—Acute Myeloid Leukemia (AML), metastatic Castration-Resistant Prostate Cancer (mCRPC) and metastatic Colorectal Cancer (mCRC),” said Dr. Thomas Adams, Executive Chairman of Trovagene. “Our Phase 1b dose-escalation segment of our AML trial is on track to reach our maximum tolerated dose and identify our recommended Phase 2 dose within the next couple of months and our Phase 2 trial in mCRPC is moving forward as planned with active enrollment and treatment of patients. We have also begun preparing for the initiation of a Phase 1b/2 trial in mCRC and plan to file our Investigational New Drug (IND) application and protocol to the FDA before the end of this year.”

Dr. Adams added, “We anticipate the following key milestones over the next twelve months: the first formal presentation of data from our AML trial at the American Society of Hematology (ASH) conference in December of 2018; reaching the maximum tolerated dose and identifying the Phase 2 dose in our AML trial in the first quarter or 2019; completing enrollment of patients in our AML and mCRPC trials by the end of the second quarter in 2019; initiating our Phase 1b/2 trial in mCRC in the first half of 2019; and reporting additional data from our AML trial and mCRPC trial throughout 2019.”

The Company has advanced its business with the following recent activities:

- **Announced New Patent Claim Allowances Affirming Broad Patent Portfolio Coverage of NPM1 Mutations by U.S. Patent and Trademark Office**

On October 24, 2018, Trovagene announced that the U.S. Patent and Trademark Office (USPTO) has allowed claims that affirms broad coverage of NPM1 mutation testing; Patent Application 14/750331, entitled “Nucleophosmin Protein (NPM) Mutants, Corresponding Gene Sequences and Uses Thereof.” This patent encompasses broad claims around the assessment of NPM1 mutational status in any cancer type, including acute myeloid leukemia (AML). This not only aligns with the Company’s current biomarker strategy and clinical development of onvansertib in AML, but also strengthens the revenue generating potential for Trovagene.

- **Announced Exclusive License Agreement with MIT for Combination Therapy of Anti-Androgens and Polo-like Kinase Inhibitors in Prostate Cancer**

On October 3, 2018, Trovagene announced that it has entered into an exclusive patent license agreement with the Massachusetts Institute of Technology (MIT). Under the agreement,

Trovagene has exclusive rights to develop combination therapies that include anti-androgen or androgen antagonist and a Polo-like Kinase (PLK) inhibitor for the treatment of cancer. The exclusive license agreement is part of the Company's strategy to explore the efficacy of Onvansertib, its first-in-class, 3rd generation, highly-selective, oral PLK1 inhibitor, in combination with anti-androgen drugs in cancers including prostate, breast, pancreatic, lung and gastrointestinal. There is a need for new therapies that effectively treat cancers that depend on internal androgen signaling, such as castration-resistant prostate cancer, as well as cancers which over-express androgen receptor (AR), or are otherwise dependent on the synthesis of steroid hormones for their growth, such as some breast cancers. In-vitro and in-vivo preclinical research demonstrates a unique synergistic effect with the combination of PLK inhibitors and anti-androgens, which was the precursor that led to the current Phase 2 trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone that is being conducted at the three Harvard Medical Cancer Centers.

- **Announced Completion of Dosing Cohort of Patients Treated with Onvansertib in Combination with Decitabine in Ongoing Phase 1b/2 AML Trial**

On September 27, 2018, Trovagene announced completion of the second dosing cohort of onvansertib, its first-in-class, 3rd generation, highly-selective oral Polo-like Kinase 1 (PLK1) Inhibitor, in combination with standard-of-care decitabine, in its Phase 1b/2 clinical trial in patients with Acute Myeloid Leukemia (AML). All three patients in the cohort successfully completed treatment with onvansertib at 18mg/m2, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with decitabine and the combination was well tolerated. The Safety Review Committee (SRC) has recommended escalating to the next dose level of onvansertib at 27mg/m2 (approximately a 50% increase) in combination with decitabine.

- **Announced Predictive Clinical Biomarker Approach to Identify Acute Myeloid Leukemia (AML) Patients Most Likely to Respond to Onvansertib**

On September 5, 2018, Trovagene announced it has developed a method for predicting response to treatment by measuring the ability of onvansertib, a first-in-class, 3rd generation, oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor, to inhibit PLK1 in patients with Acute Myeloid Leukemia (AML). PLK1 uniquely phosphorylates translational control tumor protein (TCTP) to form pTCTP and inhibition of this enzymatic activity by onvansertib appears to be predictive of patient response to treatment. In the ongoing Phase 1b/2 open label clinical trial in AML, PLK1 inhibition is being assessed 3-hours following administration, at the approximate peak concentration (C_{max}) of onvansertib. In the first six patients treated, the greatest target engagement, or inhibition of PLK1, was observed in the three patients who showed a response to treatment.

- **Announced European Commission Grants Orphan Drug Designation to Onvansertib (PCM-075) for Treatment of Acute Myeloid Leukemia in Europe**

On August 29, 2018, Trovagene announced that the European Commission (EC) has endorsed the positive opinion of the Committee for Orphan Medicinal Products (COMP) and has granted Orphan Drug Designation (ODD) for onvansertib, a first-in-class, 3rd generation, oral and highly-

selective Polo-like Kinase 1 (PLK1) inhibitor, for the treatment of patients with Acute Myeloid Leukemia (AML). Orphan drug designation by the EC provides regulatory and financial incentives to Trovagene, including reduced fees during the product development phase, direct access to centralized marketing authorization in the EU, and 10-year market exclusivity following product approval.

- **Announced Completion of Second Dosing Cohort of Patients Treated with Onvansertib (PCM-075) in Ongoing Phase 1b/2 AML Trial**

On August 16, 2018, Trovagene announced completion of the second dosing cohort of onvansertib, a first-in-class, 3rd generation, highly-selective oral Polo-like Kinase 1 (PLK1) Inhibitor, in combination with standard-of-care low-dose cytarabine (LDAC), in its Phase 1b/2 clinical trial in patients with Acute Myeloid Leukemia (AML). All three patients in the cohort successfully completed treatment with onvansertib at 18 mg/m2, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with LDAC and the combination was well tolerated. The Safety Review Committee (SRC) has recommended escalating to the next dose level of onvansertib at 27 mg/m2 (approximately a 50% increase) in combination with LDAC. Additionally, two patients in the three-patient cohort of onvansertib at 18 mg/m2 in combination with decitabine have also successfully completed at least one cycle of treatment and recruitment of the third patient to complete this cohort is in process. Four of the eleven patients treated to-date remain on treatment, three are currently receiving a second cycle of treatment and one patient is scheduled to start a fifth cycle of treatment.

- **Announced USAN Approval for "Onvansertib" as Nonproprietary Name for First-in-Class, 3rd Generation PLK1 Inhibitor, PCM-075**

On August 15, 2018, Trovagene announced that the United States Adopted Name (USAN) Council has approved "onvansertib" (pronounced on-van-ser-tib) as the nonproprietary (generic) name for its drug candidate, PCM-075. Onvansertib is a first-in-class, 3rd generation, highly selective, oral Polo Like Kinase 1 (PLK1) inhibitor, that is designed to target and inhibit cancer cell division (mitosis). Assignment of a unique generic name is a very meaningful step forward for Trovagene's drug candidate that is currently in clinical development in Acute Myeloid Leukemia and metastatic Castration-Resistant Prostate Cancer.

- **Announced Positive Opinion for Orphan Drug Designation in the European Union for PCM-075, Trovagene's Investigational Cancer Drug**

On August 1, 2018, Trovagene announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has adopted a positive opinion recommending PCM-075 for designation as an orphan medicinal product for the treatment of Acute Myeloid Leukemia (AML). PCM-075 is a first-in-class, 3rd generation, highly selective, oral Polo Like Kinase 1 (PLK1) inhibitor, that is designed to target cell division (mitosis). o be considered for Orphan Drug Designation in the EU, companies must provide data that demonstrates plausibility for use of the investigational therapy in the treatment of the disease and establish that the drug has the potential to provide relevant advantages or a major contribution to patient care over existing therapies. The opinion letter sent to Trovagene by the COMP stated that "although satisfactory methods of treatment of the condition have been

authorized in the EU, PCM-075 will be of significant benefit to those affected by AML." The COMP, a committee of the EMA, adopts an opinion on the granting of orphan drug designation, after which the opinion is submitted to the European Commission for endorsement of the opinion. The positive opinion issued by the COMP is anticipated to be adopted by the European Commission (EC) at the end of August 2018.

Third Quarter 2018 Financial Results

Total operating expenses were approximately $4.0 million for the three months ended September 30, 2018, a reduction of $2.0 million from $6.0 million for the same period in 2017. The decrease in operating expenses is attributed to optimizing operations to focus primarily on advancing development of onvansertib.

Net cash used in operating activities in the third quarter of 2018 was $3.5 million, compared to $6.6 million in the third quarter of 2017. The year-over-year reduction of $3.1 million can be attributed primarily to the elimination of expenses associated with (1) litigation settlement paid to our former CEO and CFO, (2) diagnostic programs and focus on therapeutics and the clinical development of its drug candidate, onvansertib, and (3) severance payments as a result of reduction in force.

Research and development expenses increased by approximately $0.4 million to $1.8 million for the three months ended September 30, 2018 from $1.4 million for the same period in 2017. The overall increase in research and development expenses was primarily due to the increased outside service costs for clinical studies related to the development of our drug candidate, onvansertib. We expect increases in research and development costs as we continue to advance the development of onvansertib.

Selling, general and administrative expenses decreased by approximately $2.4 million to $1.7 million for the three months ended September 30, 2018 from $4.1 million for the same period in 2017. The significant components of the decrease were primarily due to the decrease in salaries and staff costs and stock-based compensation.

The weighted average diluted shares of common stock outstanding used to calculate per share results for the three months ended September 30, 2018 was 20.6 million.

As of September 30, 2018, Trovagene had approximately $15.1 million of cash and cash equivalents.

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.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. 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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Trovagene, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except for per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Royalties	$ 73	$ 59	$ 175	$ 170
Diagnostic services	4	58	83	142
Clinical research services	11	6	42	8
Total revenues	88	123	300	320
Costs and expenses:				
Cost of revenues	27	474	597	1,428
Research and development	1,830	1,414	5,667	6,676
Selling, general and administrative	1,665	4,079	6,321	12,358
Restructuring charges (benefit)	421)	(46)	664	1,670
Total operating expenses	3,943	5,921	13,249	22,132
Loss from operations	(3,855)	(5,798)	(12,949)	(21,812)
Net interest income (expense)	86	(16)	119	(877)
(Loss) gain on change in fair value of derivative financial instruments- warrants	(2)	1,529	579	2,013))
Gain (loss) on extinguishment of debt	—	—	18	(1,656)
Other income (loss), net	2	(7)	(69)	(5)
Net loss	(3,769)	(4,292)	(12,302)	(22,337)
Preferred stock dividend	(6)	(6)	(2,788)	(18)
Net loss attributable to common stockholders	$ (3,775)	$(4,298)	$(15,090)	$(22,355)
Net loss per common share – basic and diluted	$ (0.18)	$ (1.41)	$ (1.38)	$ (8.17)
Weighted average shares outstanding – basic and diluted	20,623	3,039	10,945	2,736

Trovagene, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 15,066	$ 8,226
Accounts receivable and unbilled receivable	129	77
Prepaid expense and other assets	849	1,166
Total current assets	16,044	9,469
Property and equipment, net	1,627	2,426
Other assets	250	390
Total Assets	$ 17,921	$ 12,285
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 477	$ 825
Accrued expenses	1,718	1,455
Deferred rent	472	334
Current portion of long-term debt	—	1,332
Total current liabilities	2,667	3,946
Derivative financial instruments – warrants	70	649
Deferred rent, net of current portion	1,204	1,184
Total Liabilities	3,941	5,779
Stockholders' equity	13,980	6,506
Total liabilities and stockholders' equity	$ 17,921	$ 12,285

Trovagene, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2018	**2017**
Operating activities		
Net loss	$(12,303)	$(22,337)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	702	957
Stock based compensation expense	1,906	3,117
Change in fair value of derivative financial instruments – warrants	(579)	(2,013)
Gain (loss) on extinguishment of debt	(18)	1,656
Other non-cash items	118	638
Changes in operating assets and liabilities	587	(1,968)
Net cash used in operating activities	(9,587)	(19,950)
Investing activities:		
Net proceeds from disposal (purchase) of capital equipment	23	(136)
Net sales and maturities of short-term investments	—	24,062
Net cash provided by investing activities	23	23,926
Financing activities:		
Proceeds from sales of common stock and warrants, net of expenses	11,779	6,635
Proceeds from sales of Series B Convertible Preferred Stock, net of expenses	4,387	—
Proceeds from exercise of warrants	1,613	—
Net repayment of debt	(1,375)	(17,083)
Net cash provided by (used in) financing activities	16,404	(10,448)
Effect of exchange rate changes on cash and cash equivalents	—	(9)
Net change in cash and equivalents	(16,404)	(6,481)
Cash and cash equivalents – Beginning of period	8,226	13,915
Cash and cash equivalents – End of period	$ 15,066	$ 7,434