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): March 6, 2019

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 March 6, 2019, Trovagene, Inc. issued a press release announcing company highlights and financial results for the fourth quarter and full-year ended December 31, 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 March 6, 2019

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: March 6, 2019

TROVAGENE, INC.

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

Trovagene Announces Fourth Quarter and Full-Year 2018 Results

SAN DIEGO, CA – March 6, 2019 – 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 fourth quarter and full-year ended December 31, 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 for the treatment of cancers and indications where there is a significant need to bring new therapeutic 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, Chief Executive Officer and Chairman of Trovagene. “Our AML trial continues to advance and data shows that the combination of onvansertib and standard-of-care chemotherapy is demonstrating both a favorable safety profile and showing activity in greater than 88% of evaluable patients treated to-date, which is very encouraging. In January, we received a “study may proceed” notification from the FDA for our Phase 1b/2 trial in mCRC and expect that enrollment in this trial, which is being funded by PoC Capital, will begin mid-year. We anticipate having data readouts from our Phase 2 trial in mCRPC throughout 2019, and recently presented a poster at the Genitourinary Cancers Symposium (ASCO-GU), overviewing the trial and confirming the safety of the combination of onvansertib and Zytiga®. We will also be presenting safety and preliminary clinical data from our Phase 1b/2 trial in AML and Phase 2 trial in mCRPC at the American Association for Cancer Research (AACR) annual conference in early April, 2019.”

Dr. Adams added, “We achieved a number of key milestones in 2018, including: Successful completion of the first three dose levels, without any dose-limiting toxicities, in the Phase 1b segment of our AML trial; granting of Orphan Drug Designation in Europe for the treatment of AML; presentation of preliminary clinical data from our AML trial at the American Society of Hematology (ASH) conference in December; opening of our mCRPC Phase 2 trial to full enrollment, following confirmation that the combination of onvansertib and Zytiga® is safe and well tolerated in the safety lead-in phase; submission of a new IND and protocol for our Phase 1b/2 trial in mCRC in December; strengthening of our patent portfolio around our drug candidate, onvansertib, with the issuance of two new patents; and entering into an exclusive license agreement with MIT to develop combination therapies that include anti-androgen or androgen antagonist and a Polo-like Kinase (PLK) inhibitor (onvansertib) for the treatment of cancer.”

The Company has advanced its business in 2018, and to-date in 2019, with the following activities and milestone achievements:

- **Announced Presentation Update on Phase 2 Study of Onvansertib in Combination with Zytiga® in Patients with mCRPC at ASCO-GU**

On February 14, 2019, Trovagene announced the presentation of a poster reviewing its ongoing Phase 2 study evaluating onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC) at the Genitourinary Cancers Symposium (ASCO-GU) in San Francisco, CA. The data featured demonstrates the safety and tolerability of onvansertib in combination with Zytiga® which was confirmed in the safety lead-in portion of the trial that was completed prior to opening the trial to full enrollment. In addition, a second arm is planned with the goal of maximizing clinical activity by reducing the dosing schedule from the current 21-day cycle to a 14-day cycle.

- **Announced that Trovagene and PoC Capital Entered into an Agreement to Fund Clinical Development of Onvansertib in metastatic Coloreactal Cancer (mCRC)**

On January 29, 2019, Trovagene announced an agreement with PoC Capital to fund its Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin in patients with mCRC with a KRAS mutation. Trovagene submitted an Investigational New Drug (IND) application and protocol to the FDA on December 19, 2018, and received a "study may proceed" notification from the FDA, 28-days later, on January 16, 2019. The trial will be conducted at two prestigious cancer centers in the U.S.; USC Norris Comprehensive Cancer Center and The Mayo Clinic.

- **Announced New Patent Issued for Combination of Onvansertib and Ant--Androgen Drugs to Treat Non-Metastatic and Metastatic Prostate Cancer**

On January 23, 2019, Trovagene announced the issuance of a new patent (10,155,006), entitled *Combination Therapies and Methods of Use Thereof for Treating Cancer*, by the U.S. Patent and Trademark Office (USPTO). This patent broadens previously issued patent (9,566,280), by expanding the use of Onvansertib to encompass combination therapies with any anti-androgen and androgen antagonist drug, such as Zytiga®, Xtandi® and Erleada® for the treatment of metastatic and non-metastatic castrate-resistant prostate cancer. The issuance of this patent further strengthens Trovagene's existing intellectual property portfolio obtained with the licensing of exclusive global development and commercialization rights to onvansertib from Nerviano Medical Sciences in March, 2017.

- **Announced New Data from Phase 1b/2 Study of Onvansertib in Combination with LDAC or Decitabine Demonstrated Response to Treatment in Relapsed/Refractory AML**

On December 3, 2018, Trovagene announced presentation of data from its ongoing Phase 1b/2 study evaluating onvansertib in combination with standard-of-care chemotherapy in Acute Myeloid Leukemia (AML) at the 60th American Society of Hematology (ASH) annual meeting.

The date presented in a poster demonstrated that onvansertib, in combination with LDAC or decitabine is benefiting patients who have relapsed/refractory AML and that the combination is safe and well tolerated, with no serious adverse events (SAEs) reported to-date.

- **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 Trovagene’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.

Fourth Quarter 2018 Financial Results

Total operating expenses were approximately $4.2 million for the three months ended December 31, 2018, an increase of million $0.2 million from $4.0 million for the same period in 2017. The increase in operating expenses is attributed to advancing the onvansertib clinical development programs.

Net cash used in operating activities in the fourth quarter of 2018 was $3.6 million, compared to $3.3 million in the fourth quarter of 2017. The year-over-year increase of $0.3 million can be attributed primarily to progress made with the clinical development of its drug candidate, onvansertib.

Research and development expenses increased by approximately $1.3 million to $2.5 million for the three months ended December 31, 2018 from $1.2 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 to continue as we advance the onvansertib clinical development programs in AML, mCRPC and mCRC.

Selling, general and administrative expenses decreased by approximately $0.2 million to $1.7 million for the three months ended December 31, 2018 from $1.9 million for the same period in 2017. The reduction is primarily due to a decrease in stock-based compensation.

The weighted average diluted shares of common stock outstanding used to calculate per share results for the three months ended December 31, 2018 was 3.8 million.

As of December 31, 2018, Trovagene had approximately $11.5 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.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; 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, 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 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 December 31,		Years Ended December 31,	
	2018	2017	2018	2017
	(unaudited)			
Revenues:				
Royalties	$ 76	$ 116	$ 251	$ 286
Services	2	69	127	219
Total revenues	78	185	378	505
Costs and expenses:				
Cost of revenues	—	383	597	1,811
Research and development	2,497	1,207	8,164	7,883
Selling, general and administrative	1,685	1,874	8,006	14,232
Restructuring charges	—	505	664	2,175
Total operating expenses	4,182	3,969	17,431	26,101
Loss from operations	(4,104)	(3,784)	(17,053)	(25,596)
Net interest income (expense)	75	(9)	194	(886)
Gain on change in fair value of derivative financial instruments - warrants	38	1,388	617	3,401))
Gain (loss) on extinguishment of debt	—	—	18	(1,656)
Other loss, net	(168)	(165)	(237)	(170)
Net loss	(4,159)	(2,570)	(16,461)	(24,907)
Preferred stock dividend	(6)	(6)	(2,794)	(24)
Net loss attributable to common stockholders	$(4,165)	$(2,576)	$(19,255)	$(24,931)
Net loss per common share – basic and diluted	$ (1.09)	$ (4.61)	$ (8.26)	$ (51.76)
Weighted average shares outstanding – basic and diluted	3,832	558	2,330	482

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

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 11,453	$ 8,226
Accounts receivable and unbilled receivable	168	77
Prepaid expense	1,144	1,166
Total current assets	12,765	9,469
Property and equipment, net	1,304	2,426
Other assets	103	390
Total Assets	$ 14,172	$ 12,285
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 665	$ 825
Accrued expenses	1,814	1,455
Deferred rent	486	334
Current portion of long-term debt	—	1,332
Total current liabilities	2,965	3,946
Derivative financial instruments - warrants	32	649
Deferred rent, net of current portion	1,091	1,184
Total Liabilities	4,088	5,779
Stockholders' equity	10,084	6,506
Total liabilities and stockholders' equity	$ 14,172	$ 12,285

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

	Years Ended December 31,	
	2018	2017
Operating activities		
Net loss	$ (16,461)	$ (24,907)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	859	1,248
Stock based compensation expense	2,175	4,013
Change in fair value of derivative financial instruments - warrants	(617)	(3,401)
(Gain) loss on extinguishment of debt	(18)	1,656
Other non-cash items	764	1,236
Changes in operating assets and liabilities	98	(3,126)
Net cash used in operating activities	(13,200)	(23,281)
Investing activities:		
Net proceeds from disposal (purchase) of capital equipment	23	(100)
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	10,861
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)	(17,239)
Net cash provided by (used in) financing activities	16,404	(6,378)
Effect of exchange rate changes on cash and cash equivalents	—	8
Net change in cash and equivalents	3,227	(5,689)
Cash and cash equivalents—Beginning of period	8,226	13,915
Cash and cash equivalents—End of period	$ 11,453	$ 8,226