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, 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
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:

o Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

Item 2.02 Results of Operations and Financial Conditions

On November 7, 2019, Trovagene, Inc. issued a press release announcing company highlights and financial results for the third quarter ended September 30, 2019. 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, 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: November 7, 2019

TROVAGENE, INC.

By: /s/ Thomas Adams

Thomas Adams

Chief Executive Officer

Trovagene Announces Third Quarter 2019 Results and Highlights

SAN DIEGO (November 7, 2019) – Trovagene, Inc. (Nasdaq: TROV), a clinical-stage, Precision Cancer Medicine™ oncology therapeutics company developing drugs that target cell division (mitosis) for the treatment of various cancers including prostate, colorectal and leukemia, today announced company highlights and financial results for the third quarter ended September 30, 2019. The company is issuing this press release in lieu of conducting a conference call.

“We are pleased with the positive response to treatment with onvansertib that we are seeing across all three of our clinical trials and the continued progress and rapid advancement of our development programs,” said Dr. Thomas Adams, Chief Executive Officer and Chairman of Trovagene. “In the third quarter, we achieved a number of key milestones including: presentation of data from our ongoing Phase 2 trial in mCRPC demonstrating the efficacy of onvansertib in patients showing resistance to the ARS inhibitor, Zytiga®, even those with the highly-aggressive and difficult-to-treat androgen receptor variant 7 (AR-V7) tumor; positive data from the initial cohort of patients treated in our Phase 1b/2 trial in CRC showing decreases in tumor KRAS mutational burden in all four patients completing their first cycle of therapy; and completion of our AML Phase 1b trial and initiation of enrollment of patients in the Phase 2 continuation trial.”

The Company has advanced its business, with the following recent activities and milestone achievements:

Clinical Development:

- **Announced Positive Response to Treatment in Phase 1b/2 Trial of Onvansertib in Patients with KRAS-Mutated Metastatic Colorectal Cancer**

On October 22, 2019, Trovagene announced data demonstrating positive response to treatment in patients enrolled in its Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for second-line treatment of KRAS-mutated metastatic colorectal cancer (mCRC). Decreases in tumor KRAS mutational burden in response to treatment was observed in all four patients who completed their first cycle of therapy with the combination regimen, as measured by quantitative analysis of circulating tumor DNA (ctDNA).

- **Announced Data Presented at ESMO Provides Rationale for Clinical Trial of Onvansertib in Subset of Patients with Highly-Aggressive Triple-Negative Breast Cancer (TNBC)**

On October 2, 2019, Trovagene announced the presentation of preclinical data demonstrating significant tumor regression with the combination of onvansertib and paclitaxel, versus either agent alone, in models of triple-negative breast cancer (TNBC).

- **Announced Presentation of Overview of Phase 1b/2 Trial of Onvansertib in Patients with KRAS-Mutated Metastatic Colorectal Cancer (mCRC) at ESMO**

On October 1, 2019, Trovagene announced the presentation of its Phase 1b/2 trial evaluating onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) in patients with KRAS-mutated metastatic Colorectal Cancer (mCRC). The trial overview, featured in a poster presentation at the European Society for Medical Oncology (ESMO) Annual Congress showed the supportive preclinical data underlying the scientific rationale for the trial, as well as the trial design and primary safety and efficacy endpoints. In addition, early biomarker data demonstrates proof-of-concept that patient response can be monitored by a non-invasive blood test to quantitate the KRAS mutation burden within one week following initial dosing with onvansertib.

- **Announced Positive Data from Trovagene Phase 1b/2 Study of Onvansertib in Acute Myeloid Leukemia (AML) was Featured in an Oral Presentation at ESMO**

On September 30, 2019, Trovagene announced that results from the Company's Phase 1b/2 study of onvansertib in patients with relapsed/refractory acute myeloid leukemia (AML) were presented in an oral plenary session at the 2019 European Society for Medical Oncology (ESMO) Conference in Barcelona, Spain, on Saturday, September 28th. The presentation highlighted the favorable safety profile and clinical efficacy of onvansertib, as well as correlative biomarker data from the recently completed Phase 1b trial.

- **Announced Successful Completion of Phase 1b Trial of Onvansertib in Acute Myeloid Leukemia (AML) and Initiation of Patient Enrollment in Phase 2**

On September 19, 2019, Trovagene announced the successful completion of its Phase 1b trial of onvansertib in combination with standard-of-care chemotherapy in acute myeloid leukemia (AML) and initiation of patient enrollment in Phase 2. The Phase 1b dose-escalation trial confirmed that onvansertib in combination with standard-of-care chemotherapy is safe and well tolerated. Additionally, the primary efficacy endpoint of objective response (CR + CRi) was achieved in 5 of 21 patients treated with onvansertib + decitabine, indicating anti-leukemic activity in this difficult-to-treat relapsed/refractory AML population. Importantly, 30% of patients treated were biomarker positive, which was associated with an increase in response to treatment as measured by decreases in bone marrow blasts and the rate of complete response.

- **Announced Presentation of Positive Clinical Data from Ongoing Phase 2 Study of Onvansertib in Metastatic Castration-Resistant Prostate Cancer (mCRPC)**

On August 26, 2019, Trovagene announced the presentation of positive clinical data from its ongoing Phase 2 clinical trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone, an androgen-receptor signaling (ARS) inhibitor, in metastatic Castration-Resistant Prostate Cancer (mCRPC), at the 20th Asia-Pacific Prostate Cancer Conference in Melbourne, Australia. These data demonstrate the efficacy of onvansertib in patients showing resistance to the ARS inhibitor, Zytiga® (Johnson & Johnson), including those with the highly-aggressive and difficult-to-treat androgen receptor variant 7 (AR-V7) tumor.

- **Announced Initiation of Enrollment for Phase 1b/2 Clinical Trial in KRAS-Mutated Colorectal Cancer at Leading Cancer Centers**

On July 9, 2019, Trovagene announced the initiation of patient enrollment of its Phase 1b/2 study of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for second-line treatment of patients with metastatic colorectal cancer (mCRC) with a KRAS mutation (NCT03829410). The trial is being conducted at USC Norris Comprehensive Cancer Center, Hoag Cancer Center and The Mayo Clinic, under the leadership of recognized colorectal cancer key opinion leaders, Heinz-Josef Lenz, MD, FACP, Section Head of GI Oncology and Co-Director of the Colorectal Center at USC Norris, and Afsaneh Barzi, MD, PhD, oncologist at USC Norris and principal investigator of the trial.

Financial:

- **Announced $5.0 Million Private Placement Priced At Market**

On October 25, 2019, Trovagene announced that it has entered into a private placement with certain institutional investors for gross proceeds of approximately $5.0 million. We sold an aggregate of 2,756,340 shares of common stock (including common stock equivalents) and Series G and Series H Warrants to purchase 2,756,340 shares of Common Stock for each class of Warrant.

- **Announced Equity Investments of $1.5 Million at Premium to Market Price from Institutional Investor, Lincoln Park Capital**

On August 21, 2019, Trovagene announced that it has entered into a definitive purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") an existing institutional investor, in which Lincoln Park agreed to purchase in a registered direct offering shares of common stock and pre-funded warrants. In a concurrent private placement, Lincoln Park agreed to purchase warrants to purchase shares of common stock.

Third Quarter 2019 Financial Results

Total operating expenses were approximately $4.3 million for the three months ended September 30, 2019, an increase of $0.3 million from $4.0 million for the same period in 2018. The increase in operating expenses is primarily attributed to advancing clinical programs and associated costs, offset by restructuring charges incurred in 2018.

Net cash used in operating activities in the third quarter of 2019 was approximately $3.2 million, compared to $3.5 million in the same period in 2018. The year-over-year decrease of $0.3 million can be attributed primarily to changes in assets and liabilities, and partially offset by the increase in development expenses as we advance our clinical trials.

Research and development expenses increased by approximately $1.0 million to $2.8 million for the three months ended September 30, 2019 from $1.8 million for the same period in 2018. The overall increase in expenses was primarily due to costs associated with our clinical programs and outside services for two ongoing clinical trials and the start of a third clinical trial related to the development of our drug candidate, onvansertib. We expect increases in research and development costs 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 $1.5 million for the three months ended September 30, 2019 from $1.7 million for the same period in 2018. The decrease was primarily due to decreases in facilities and other costs, and reduction in salaries and staff costs.

The weighted average diluted shares of common stock outstanding used to calculate per share results for the three months ended September 30, 2019 was 5.8 million shares.

As of September 30, 2019, Trovagene had approximately $9.0 million of cash and cash equivalents.

About Trovagene, Inc.

Trovagene is a clinical-stage, oncology therapeutics company, taking a Precision Cancer Medicine™ approach to develop drugs that target mitosis (cell division) to treat various types of cancer, including prostate, colorectal and leukemia. 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; 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 Statements of Operations

(in thousands, except for per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Royalties	$ 52	$ 73	$ 151	$ 175
Services and other	—	15	1	125
Total revenues	52	88	152	300
Costs and expenses:				
Cost of revenues	—	27	—	597
Research and development	2,819	1,830	8,298	5,667
Selling, general and administrative	1,440	1,665	4,243	6,321
Restructuring charges	—	421	—	664
Total operating expenses	4,259	3,943	12,541	13,249
Loss from operations	(4,207)	(3,855)	(12,389)	(12,949)
Net interest income	54	86	188	119
Gain (loss) from change in fair value of derivative financial instruments—warrants	13	(2)	27	579
Gain on extinguishment of debt	—	—	—	18
Other (loss) income, net	(1)	2	2	(69)
Net loss	(4,141)	(3,769)	(12,172)	(12,302)
Preferred Stock Dividend	(6)	(6)	(286)	(2,788)
Net loss attributable to common stockholders	$ (4,147)	$ (3,775)	$ (12,458)	$ (15,090)
Net loss per common share — basic	$ (0.71)	$ (1.10)	$ (2.46)	$ (8.27)
Net loss per common share — diluted	$ (0.71)	$ (1.10)	$ (2.46)	$ (8.27)
Weighted-average shares outstanding — basic	5,823	3,437	5,057	1,824
Weighted-average shares outstanding — diluted	5,823	3,437	5,057	1,824

Trovagene, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 9,032	$ 11,453
Accounts receivable and unbilled receivable	152	168
Prepaid expenses	793	1,144
Total current assets	9,977	12,765
Property and equipment, net	271	1,304
Operating lease right-of-use assets	1,503	—
Other assets	171	103
Total Assets	$ 11,922	$ 14,172
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 492	$ 665
Accrued expenses	2,842	1,814
Operating lease liabilities	836	—
Deferred rent, current portion	—	486
Total current liabilities	4,170	2,965
Derivative financial instruments—warrants	5	32
Operating lease liabilities, net of current portion	1,091	—
Deferred rent, net of current portion	—	1,091
Total Liabilities	5,266	4,088
Stockholders' equity	6,656	10,084
Total liabilities and stockholders' equity	$ 11,922	$ 14,172

Trovagene, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (12,172)	$ (12,303)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	130	702
Stock based compensation expense	615	1,906
Change in fair value of derivative financial instruments—warrants	(27)	(579)
Release of clinical trial funding commitment	509	—
Loss on extinguishment of debt	—	(18)
Other non-cash items	—	118
Changes in operating assets and liabilities	955	587
Net cash used in operating activities	(9,990)	(9,587)
Investing activities:		
Net proceeds from disposal (purchase) of capital equipment	(68)	23
Net cash used in investing activities	(68)	23
Financing activities:		
Proceeds from sales of common stock and warrants, net of expenses	4,386	11,779
Proceeds from sales of Series B Convertible Preferred Stock, net of expenses	—	4,387
Costs related to the clinical trial funding commitment	(40)	—
Proceeds from exercise of warrants	3,291	1,613
Repayment of debt	—	(1,375)
Net cash provided by financing activities	7,637	16,404
Net change in cash and cash equivalents	(2,421)	6,840
Cash and cash equivalents—Beginning of period	11,453	8,226
Cash and cash equivalents—End of period	$ 9,032	$ 15,066