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): May 8, 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 May 8, 2018, Trovagene, Inc. issued a press release announcing company highlights and financial results for the first quarter ended March 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 May 8, 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: May 9, 2018

TROVAGENE, INC.

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

Trovagene Announces First Quarter 2018 Highlights and Financial Results

SAN DIEGO, CA – May 8, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, developing targeted therapies to treat hematologic and solid tumor cancers, today announced company highlights and financial results for the first quarter ended March 31, 2018. The company is issuing this press release in lieu of conducting a conference call.

“We are pleased with the rapid progress we are making in executing our clinical development programs in both hematologic and solid tumor cancers as well as the support from investigators for our lead drug candidate, PCM-075,” said Bill Welch, Chief Executive Officer of Trovagene. “The first dosing cohort of PCM-075 in combination with low-dose cytarabine (LDAC) in our Phase 1b/2 Acute Myeloid Leukemia (AML) study is fully enrolled, and we anticipate opening the next dosing cohort to enrollment this quarter. Our second study, a Phase 2 trial of PCM-075 in combination with abiraterone acetate (Zytiga®) in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC), is on track to begin enrolling patients later this year with the Harvard Medical Cancer Centers.”

Trovagene reported a net loss of $4.8 million, or $0.09 per diluted share in the first quarter of 2018, as compared to a net loss of $10.0 million, or $0.32 per diluted share, for the same quarter of 2017. Net cash used in operating activities in the first quarter of 2018 was $2.9 million, compared to $8.8 million in the first quarter of 2017. These year-over year, and quarter-over-quarter, reductions are attributed primarily to the elimination of expenses associated with diagnostic programs and transition of the Company to focus on therapeutics and the clinical development of its lead drug candidate, PCM-075.

During 2018 the Company has advanced its business with the following activities:

- Announced initiation plans for a Phase 2 clinical trial evaluating the combination of PCM-075 and abiraterone acetate (Zytiga®- Johnson & Johnson) in patients with mCRPC. This study is designed to have 3 clinical sites, with Dr. David Einstein at the Genitourinary Oncology Program at Beth Israel Deaconess Medical Center and Harvard Medical School as the principal investigator.
- Presented data showing synergy of PCM-075 in combination with Zytiga® in a Castration-Resistant Prostate Cancer Model at the 2018 Genitourinary Cancers Symposium (ASCO GU).
- Activated six additional clinical trial sites, for a total of eight sites actively screening and enrolling patients, for our Phase1b/2 multicenter trial of PCM-075 in patients with AML.

- Announced that the first patient successfully completed the cycle 1 of treatment in our Phase1b/2 multicenter trial of PCM-075 in combination with low-dose cytarabine in patients with AML. The patient tolerated the combination well and correlative analyses of blood samples, taken at specified time points, also indicated activity on circulating leukemic cells.
- Announced that two additional patients in the initial dose escalation cohort are on treatment and receiving a 12 mg/m^2 oral, daily dose of PCM-075 (Days 1-5 in a 28-day cycle) in combination with LDAC, completing enrollment of the three patients in this cohort. Additionally, patient enrollment is also complete in the first Phase 1b dose-escalation cohort of three patients to receive a 12 mg/m^2 oral, daily dose of PCM-075 (Days 1-5 in a 28-day cycle) in combination with decitabine. Subsequent to this announcement, one patient in the decitabine arm was removed from the trial prior to the end of the 28-day cycle due to unrelated disease progression and will be replaced to complete this dosing cohort.
- Presented data showing that PCM-075 exhibits synergistic activity when combined with FLT3 inhibitors in a human xenograft AML model, at the American Association for Cancer Research (“AACR”) Annual Meeting in Chicago, IL.
- Presented the methodology developed to track dynamic changes in blood leukemic cells, genomic alterations and PLK1 inhibition in patients treated with PCM-075 in combination with LDAC in its Phase 1b/2 clinical trial in AML, at the AACR Annual Meeting in Chicago, IL.

First Quarter 2018 Financial Results

- Trovagene reported a net loss of $4.8 million, or $0.09 per diluted share in the first quarter of 2018, as compared to a net loss of $10.0 million, or $0.32 per diluted share, for the same quarter of 2017.
- Total operating expenses were approximately $4.8 million for the three months ended March 31, 2018, a reduction of $5.4 million from $10.2 million for the same period in 2017. Part of the decrease in cash used in operating activities was because we did not have the restructuring expenses in 2018 that we incurred in 2017 ($1.7 million for termination of employees and other costs related to restructuring of the Company from a diagnostic to therapeutics focus).
- Net cash used in operating activities in the first quarter of 2018 was $2.9 million, compared to $8.8 million in the first quarter of 2017. The year-over-year and quarter-over-quarter reduction can be attributed primarily to the elimination of expenses associated with diagnostic programs and transition to a focus on therapeutics and the clinical development of its lead drug candidate, PCM-075.
- Net cash provided by financing activities in the first quarter of 2018 was $1.3 million as compared to $0.2 million used in financing activities in the same period of 2017. Financing activities during the three months ended March 31, 2018 related primarily to the proceeds from exercise of warrants.

- The weighted average diluted shares of common stock outstanding used to calculate per share results was 55.4 million.
- As of March 31, 2018, Trovagene had approximately $6.7 million of cash and cash equivalents. As of April 30, 2018, the Company has received approximately $1.6 million upon exercise of 5,681,667 warrants in connection with the December 2017 public offering.

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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Trovagene, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except for per share amounts)

	Three Months Ended March 31,	
	2018	2017
Revenues:		
Royalties	$ 49	$ 66
Diagnostic services	40	29
Clinical research services	11	—
Total revenues	100	95
Costs and expenses:		
Cost of revenues	366	616
Research and development	1,884	4,280
Selling, general and administrative	2,505	3,605
Restructuring charges	—	1,720
Total operating expenses	4,755	10,221
Loss from operations	(4,655)	(10,126)
Net interest expense	(2)	(429)
Loss (gain) from change in fair value of derivative financial instruments- warrants	(130)	556
Other income	1	—
Net loss	(4,786)	(9,999)
Preferred stock dividend	(6)	(6)
Net loss attributable to common stockholders	$ (4,792)	$(10,005)
Net loss per common share - basic	$ (0.09)	$ (0.32)
Net loss per common share - diluted	$ (0.09)	$ (0.32)
Weighted average shares outstanding - basic	55,364	30,961
Weighted average shares outstanding - diluted	55,364	30,961

Trovagene, Inc.

Condensed Consolidated Balance Sheets

(in thousands)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 6,657	$ 8,226
Accounts receivable and unbilled receivable	114	77
Prepaid expense and other current assets	1,068	1,166
Total current assets	7,834	9,469
Property and equipment, net	2,224	2,426
Other assets	345	390
Total Assets	$ 10,408	$ 12,285
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 652	$ 825
Accrued expenses	1,685	1,455
Deferred rent	342	334
Current portion of long-term debt	1,175	1,332
Total current liabilities	3,854	3,946
Derivative financial instruments - warrants	779	649
Deferred rent, net of current portion	1,096	1,184
Total Liabilities	5,729	5,779
Stockholders' equity	4,679	6,506
Total Liabilities and Stockholders' Equity	$ 10,408	$ 12,285

Trovagene, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

	Three Months Ended March 31,	
	2018	**2017**
Operating activities		
Net loss	$(4,786)	$ (9,999)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	252	331
Stock based compensation expense	1,406	921
Change in fair value of derivative financial instruments - warrants	130	(556)
Other non-cash items	(79)	775
Changes in operating assets and liabilities	221	(230)
Net cash used in operating activities	(2,856)	(8,758)
Investing activities:		
Capital expenditures, net	(5)	(11)
Net maturities of short-term investments	—	5,195
Net cash (used in) provided by investing activities	(5)	5,184
Financing activities:		
Proceeds from exercise of warrants	1,449	—
Repayment of debt	(157)	(157)
Net cash provided by (used in) financing activities	1,292	(157)
Effect of exchange rate changes on cash and cash equivalents	—	(1)
Net change in cash and equivalents	(1,569)	(3,732)
Cash and cash equivalents—Beginning of period	8,226	13,915
Cash and cash equivalents—End of period	$ 6,657	$10,183