
**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): February 26, 2018

Trovagene, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-35558
(Commission
File Number)

27-2004382
(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 February 26, 2018, Trovogene, Inc. issued a press release announcing company highlights and financial results for the fourth quarter and full-year ended December 31, 2017. 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 Trovogene, Inc. dated February 26, 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: February 26, 2018

TROVAGENE, INC.

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



Trovagene Announces Fourth Quarter and Full-Year 2017 Results

SAN DIEGO, CA – February 26, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage precision medicine biotechnology company, developing targeted therapeutics to treat hematologic and solid tumor cancers, today announced company highlights and financial results for the fourth quarter and full-year ended December 31, 2017. The company is issuing this press release in lieu of conducting a conference call.

“I’m very proud of our transformation and accomplishments in 2017 and excited as we begin 2018 executing on strong clinical development programs for our lead drug candidate, PCM-075, with two active clinical studies underway,” said Bill Welch, Chief Executive Officer of Trovagene. “The first study is TROV-052 (ClinicalTrials.gov Identifier NCT03303339), a Phase 1b/2 open-label clinical trial of PCM-075 in patients with Acute Myeloid Leukemia (AML) in combination with standard-of-care. The second study is our UNITE (TROV-053), Phase 2 open-label clinical trial of PCM-075 in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC) in combination with abiraterone acetate (Zytiga®) and prednisone (ClinicalTrials.gov Identifier: NCT03414034).”

Trovagene reported a net loss of \$2.6 million, or \$0.06 per diluted share in the fourth quarter of 2017, as compared to a net loss of \$8.5 million, or \$0.34 per diluted share, for the same quarter of 2016. Net cash used in operating activities in the fourth quarter of 2017 was \$3.3 million, compared to \$9.0 million in the fourth quarter of 2016. These quarter-over-quarter reductions are attributed primarily to the reductions of sales, marketing and research expenses associated with diagnostic programs in order to focus on PCM-075 clinical studies.

“We are also excited about the positive preclinical data demonstrating significant synergy of PCM-075 in combination with chemotherapies and targeted therapeutics, including cytarabine and abiraterone acetate, which are used in AML and mCRPC, respectively,” said Mark Erlander, PhD, Chief Scientific Officer of Trovagene. “We believe the selective nature of PCM-075 to PLK1 may allow for enhanced combination treatments over standard-of-care in a variety of hematologic and solid tumor cancers where there are high medical needs.”

During the year ended December 31, 2017, the Company advanced its business with the following activities:

- Activated the first two clinical trial sites for the Phase 1b/2 multicenter trial of PCM-075 in patients with Acute Myeloid Leukemia (AML). As of today, Trovagene has four clinical trial sites currently screening and enrolling patients with four additional sites planned to be activated by the end of the first quarter.

- Announced the UNITE clinical study, “A Phase 2 Study to Understand the Novel Combination of PCM-075 and Abiraterone and the Opportunity to Improve Treatment and Extend Response in Patients with Metastatic Castration-Resistant Prostate Cancer.” The study will enroll 25 patients with mCRPC who are showing early signs of disease progression while on abiraterone/prednisone therapy and will evaluate the proportion of patients achieving disease control after 12 weeks of study treatment.
- Presented data showing sensitivity of TNBC cell lines to PCM-075 and Synergy with Zytiga® at San Antonio Breast Cancer Symposium. We also announced preclinical research demonstrating synergy of PCM-075 with Zytiga® in Castration-Resistant Prostate Cancer tumor cells.
- Announced that the FDA granted Orphan Drug Designation to PCM-075 for the treatment of patients with AML.
- Strengthened our Board of Directors with the appointment of Athena Countouriotis, M.D. Dr. Countouriotis brings significant experience in oncology clinical development and orphan indications.
- Announced PCM-075 synergy with a HDAC Inhibitor in Non-Hodgkin Lymphoma Cell Lines. Additionally, PCM-075 demonstrates synergy in combination with more than ten chemotherapeutic and targeted therapies across a broad range of solid tumor and hematologic cancers, including the announcement of preclinical in vivo AML data showing that PCM-075 significantly enhances the efficacy of a FLT3 inhibitor in combination therapy.
- Announced FDA approval of IND for Phase 1b/2 trial of PCM-075 in patients with AML.
- Announced peer-reviewed publication of first-in-human Phase 1 trial results with PCM-075 in the journal Investigational New Drugs. The data from the trial demonstrated PCM-075’s potential as safe and effective treatment for solid tumor and hematological malignancies.
- Executed a supplier agreement with NerPharMa, S.r.l., a pharmaceutical manufacturing company and a subsidiary of Nerviano Medical Sciences S.r.l., to manufacture drug product for PCM-075.
- Entered into a license agreement with Nerviano that grants us exclusive global development and commercialization rights to NMS-1286937, which we refer to as PCM-075. PCM-075 is an oral, investigative drug and a highly-selective PLK 1 inhibitor for the treatment of AML.

Fourth Quarter 2017 Financial Results

- Trovogene reported a net loss of \$2.6 million, or \$0.06 per diluted share in the fourth quarter of 2017, as compared to a net loss of \$8.5 million, or \$0.34 per diluted share, for the same quarter of 2016.
- Total operating expenses were approximately \$4.0 million for the three months ended December 31, 2017, a reduction of \$5.9 million from \$9.9 million for the same period in 2016.

- Net cash used in operating activities in the fourth quarter of 2017 was \$3.3 million, compared to \$9.0 million in the fourth quarter of 2016. The quarter-over-quarter reduction can be attributed primarily to a decrease in selling and marketing expenses as a result of reduction in force and a decrease in research and development costs due to a shift in focus of the Company.
- Net cash provided by financing activities in the fourth quarter of 2017 was \$4.1 million as compared to \$0.1 million used in financing activities in the same period of 2016. The increase is primarily due to the sale of securities during December fundraising activity.
- The weighted average diluted shares of common stock outstanding used to calculate per share results was 40.2 million.
- As of December 31, 2017, Trovogene had approximately \$8.2 million of cash and cash equivalents. As of February 20, 2018, the Company has received approximately \$0.5 million of additional cash to the year end \$8.2 million upon exercise of 1,814,167 warrants in connection with the December 2017 public offering.

Year-End 2017 Financial Results

- Trovogene reported a net loss of \$24.9 million, or \$0.72 per diluted share, as compared to a net loss of \$39.2 million, or \$1.37 per diluted share, for the year ended December 31, 2016. The decrease in net loss is primarily due to decreased expenses related to sales and marketing, general and administrative and research and development versus the prior year.
- The net cash used in operating activities in 2017 was \$23.3 million, compared to \$31.0 million in 2016.

About Trovogene, Inc.

Trovogene is a precision medicine biotechnology company developing oncology therapeutics for improved cancer care by leveraging its proprietary Precision Cancer Monitoring® (PCM) technology in tumor genomics. Trovogene has broad intellectual property and proprietary technology to measure circulating tumor DNA (ctDNA) in urine and blood to identify and quantify clinically actionable markers for predicting response to cancer therapies. Trovogene offers its PCM technology at its CLIA/CAP – accredited laboratory and plans to continue to vertically integrate its PCM technology with precision cancer therapeutics. For more information, please visit <https://www.trovogene.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 Trovogene’s expectations, strategy, plans or intentions. These forward-looking statements are based on Trovogene’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 Trovogene'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 Trovogene'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 Trovogene 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,		Year Ended December 31,	
	2017	2016	2017	2016
Revenues:				
Royalties	\$ 116	\$ 50	\$ 286	\$ 258
Diagnostic services	54	17	196	86
Clinical research services	15	1	23	37
Total revenues	<u>185</u>	<u>68</u>	<u>505</u>	<u>381</u>
Costs and expenses:				
Cost of revenues	383	587	1,811	1,730
Research and development	1,207	3,785	7,883	15,007
Selling and marketing	292	2,396	2,735	11,523
General and administrative	1,582	2,292	11,497	11,476
Restructuring charges	505	790	2,175	790
Total operating expenses	<u>3,969</u>	<u>9,850</u>	<u>26,101</u>	<u>40,526</u>
Loss from operations	<u>(3,784)</u>	<u>(9,782)</u>	<u>(25,596)</u>	<u>(40,145)</u>
Net interest expense	(9)	(408)	(886)	(1,376)
Gain on change in fair value of derivative financial instruments - warrants	1,388	1,787	3,401	2,462
Loss on extinguishment of debt	—	—	(1,656)	—
Other loss, net	(165)	(145)	(170)	(145)
Net loss	<u>\$ (2,570)</u>	<u>\$ (8,548)</u>	<u>\$ (24,907)</u>	<u>\$ (39,204)</u>
Preferred stock dividend	(6)	(6)	(24)	(24)
Net loss attributable to common stockholders	<u>\$ (2,576)</u>	<u>\$ (8,554)</u>	<u>\$ (24,931)</u>	<u>\$ (39,228)</u>
Net loss per common share - basic	<u>\$ (0.06)</u>	<u>\$ (0.28)</u>	<u>\$ (0.72)</u>	<u>\$ (1.30)</u>
Net loss per common share - diluted	<u>\$ (0.06)</u>	<u>\$ (0.34)</u>	<u>\$ (0.72)</u>	<u>\$ (1.37)</u>
Weighted average shares outstanding - basic	<u>40,182</u>	<u>30,639</u>	<u>34,680</u>	<u>30,175</u>
Weighted average shares outstanding - diluted	<u>40,182</u>	<u>30,712</u>	<u>34,680</u>	<u>30,281</u>

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

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	\$ 8,226	\$ 37,893
Accounts receivable	77	100
Prepaid expense and other current assets	1,166	957
Total current assets	9,469	38,950
Property and equipment, net	2,426	3,827
Other assets	390	1,173
Total Assets	\$ 12,285	\$ 43,950
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 825	1,131
Accrued expenses	1,455	4,021
Deferred rent	334	285
Current portion of long-term debt	1,332	2,360
Total current liabilities	3,946	7,797
Long-term debt, less current portion	—	14,176
Derivative financial instruments - warrants	649	835
Deferred rent, net of current portion	1,184	1,374
Total Liabilities	5,779	24,182
Stockholders' equity	6,506	19,768
Total liabilities and stockholders' equity	\$ 12,285	\$ 43,950

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

	Year Ended December 31,	
	2017	2016
Operating activities		
Net loss	\$(24,907)	\$(39,204)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,248	1,070
Stock based compensation expense	4,013	7,504
Change in fair value of derivative financial instruments - warrants	(3,401)	(2,462)
Loss on extinguishment of debt	1,656	—
Other non-cash items	1,236	964
Changes in operating assets and liabilities	(3,126)	1,088
Net cash used in operating activities	<u>(23,281)</u>	<u>(31,040)</u>
Investing activities:		
Capital expenditures, net	(100)	(823)
Net sales and maturities (purchase) of short-term investments	24,062	(24,010)
Net cash provided by (used in) investing activities	<u>23,962</u>	<u>(24,833)</u>
Financing activities:		
Proceeds from sales of common stock, net of expenses	10,861	2,285
Proceeds from exercise of options	—	367
Net repayment of debt	(17,239)	(351)
Net cash used in (provided by) financing activities	<u>(6,378)</u>	<u>2,301</u>
Effect of exchange rate changes on cash and cash equivalents	8	(6)
Net change in cash and equivalents	<u>(5,689)</u>	<u>(53,578)</u>
Cash and cash equivalents—Beginning of period	13,915	67,493
Cash and cash equivalents—End of period	<u>\$ 8,226</u>	<u>\$ 13,915</u>