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 7, 2020**

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 May 7, 2020, Trovagene, Inc. issued a press release announcing company highlights and financial results for the first quarter ended March 31, 2020. 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 7, 2020

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 7, 2020

TROVAGENE, INC.

By: /s/ Thomas Adams

Thomas Adams

Chief Executive Officer

Trovagene Announces First Quarter 2020 Results and Highlights

SAN DIEGO (May 7, 2020) - Trovagene, Inc. (Nasdaq: TROV), a clinical-stage oncology therapeutics company developing drugs to treat cancers with the greatest medical need for new treatment options, including colorectal cancer, prostate cancer and leukemia, today announced company highlights and financial results for the first quarter ended March 31, 2020. The company is issuing this press release in lieu of conducting a conference call.

“We are pleased with the promising data we are seeing in all three of our ongoing clinical programs and the continued support from our clinical trial sites and investigators,” said Dr. Thomas Adams, Executive Chairman of Trovagene. “We began the year with an update from our trial in KRAS-mutated metastatic colorectal cancer (mCRC) at the ASCO-GI conference, and most recently presented new data from this trial in an oral presentation at the American Association for Clinical Research (AACR) annual meeting, demonstrating consistent tumor shrinkage, across KRAS mutations, and progression-free survival exceeding that of current standard-of-care. Treatment with onvansertib has been so successful in KRAS-mutated mCRC, an indication which until now had a response rate of only 4% and a very poor prognosis, that one of the patients in our trial went on to have successful curative surgery, an unlikely event in this patient population. We also continue to see the safety and efficacy of onvansertib in our two Phase 2 trials; Zytiga®-resistant castration-resistant prostate cancer (mCRPC) and relapsed/refractory acute myeloid leukemia (AML), with additional data readouts from all three trials anticipated throughout 2020.”

The Company has advanced its business to-date in 2020, with the following activities and milestone achievements:

- **Announced company name change from Trovagene, Inc. to Cardiff Oncology, Inc. and appointment of Mark Erlander, PhD, as Chief Executive Officer, with an effective date of Friday, May 8, 2020**

On May 6, 2020, we announced a change in our Company name change from Trovagene, Inc. to Cardiff Oncology, Inc., and a change in leadership with Mark Erlander, PhD, assuming the role of Chief Executive Officer. Thomas Adams, PhD, our current Chairman and CEO will transition his role to Executive Chairman. Our new name reflects the Company’s mission and commitment to turning the tide on cancer by advancing the development of onvansertib, our first-in-class, third-generation, oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor, across multiple cancer types. Our company name and leadership changes will be effective as of Friday, May 8, 2020. In connection with the new corporate name, the Company’s Nasdaq ticker symbol will change to ‘CRDF’ and will be effective at the open of the market on Friday, May 8, 2020.

- **Announced presentation of data from clinical trial in KRAS-mutated metastatic colorectal cancer demonstrating consistent tumor regression across KRAS mutation subtypes and durable response**

On April 28, 2020, we announced new positive results from our ongoing Phase 1b/2 clinical trial of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for second-line treatment of patients with KRAS-mutated metastatic colorectal cancer (mCRC). The data were featured in a virtual oral presentation, delivered by Dr. Afsaneh Barzi, at the American Association for Cancer Research (AACR) conference on Monday, April 27, 2020. The ongoing Phase 1b/2 trial has enrolled 12 patients with 88% response in 7 of 8 evaluable patients to-date: 3 patients exhibiting a partial response (PR), and 4 patients with stable disease (SD). Data show median progression-free survival (PFS) of at least 6.5 months with 6 patients continuing on treatment to-date, and one patient having gone on to successful curative surgery.

The level of KRAS mutations in blood during treatment is the biomarker used in this trial, with a decrease to non-detectable level in cycle one of treatment being predictive of future tumor regression and response.

- **Announced expansion of Board of Directors with the addition of three industry leaders**

On April 22, 2020, we announced the election of three new independent Directors to our Board of Directors; Dr. James Armitage, Ms. Lâle White and Dr. Gary Pace. Each new Director brings extensive and relevant experience to the Company and will provide valuable perspective and meaningful impact as we enhance value to our shareholders.

- **Announced presentation of Phase 2 data demonstrating the ability of onvansertib to overcome Zytiga®-resistance and provide clinical benefit for mCRPC patients**

On February 13, 2020, we announced the presentation of positive data from our ongoing Phase 2 trial of onvansertib in combination with Zytiga® for the treatment of patients with Zytiga®-resistant mCRPC. The data demonstrated the efficacy of onvansertib in Zytiga®-resistant mCRPC across known androgen receptor resistance mechanisms. Additionally, the appearance of an onvansertib-induced decrease in circulating tumor cells (CTCs) was established as a surrogate for efficacy, and was associated with greater progression-free survival in mCRPC patients.

- **Announced that Trovagene received approximately $1.45 million from exercise of warrants**

On January 29, 2020, we announced that the Company received approximately $1.45 million in proceeds from holders exercising common stock purchase warrants at an exercise price of $1.56 per share. The warrants were issued as part of the units sold to certain institutional investors in October, 2019. Additionally, we received two separate individual investments of approximately $1.0 million each in March and April, respectively, for a total of approximately $3.45 million to-date in 2020.

First Quarter 2020 Financial Results

Total operating expenses were approximately $4.2 million for the three months ended March 31, 2020, an increase of $0.2 million from $4.0 million for the same period in 2019. The increase in operating expenses is attributed to advancing the onvansertib clinical development programs.

Net cash used in operating activities in the first quarter of 2020 and the first quarter of 2019 was $3.4 million.

Research and development expenses increased by approximately $0.1 million to $2.7 million for the three months ended March 31, 2020 from $2.6 million for the same period in 2019. The increase in research and development expenses was primarily due to costs associated with advancing clinical studies related to the development of our drug candidate, onvansertib. We expect increases in research and development costs to continue as we advance our onvansertib clinical development programs in mCRC, mCRPC and AML.

Selling, general and administrative expenses increased by approximately $0.1 million to $1.5 million for the three months ended March 31, 2020 from $1.4 million for the same period in 2019. The increase is primarily due to an increase in facilities and other costs, and outside services.

The weighted average basic and diluted shares of common stock outstanding used to calculate per share results for the three months ended March 31, 2020 was 9.9 million.

As of March 31, 2020, Trovagene had approximately $9.3 million of cash and cash equivalents.

About Trovagene, Inc.

Trovagene is a clinical-stage biotechnology company with the singular mission of developing new treatment options for cancer patients in indications with the greatest medical need. Our goal is to overcome resistance, improve response to treatment and increase overall survival. We are developing onvansertib, a first-in-class, third-generation Polo-like Kinase 1 (PLK1) inhibitor, in combination with standard-of-care chemotherapy and targeted therapeutics. Our clinical development programs incorporate tumor genomics and biomarker technology to enable assessment of patient response to treatment. We have three ongoing clinical programs that are demonstrating the safety and efficacy of onvansertib: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® in KRAS-mutated metastatic colorectal cancer (mCRC); a Phase 2 study of onvansertib in combination with Zytiga® (abiraterone)/prednisone in Zytiga-resistant metastatic castration-resistant prostate cancer (mCRPC); and a Phase 2 study of onvansertib in combination with decitabine in relapsed or refractory acute myeloid leukemia (AML). 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; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase our costs and expenses; 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, 2019, 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.

Trovagene Contact:
Vicki Kelemen
VP, Clinical Development and Investor Relations
858-952-7652
vkelemen@trovagene.com

Trovagene, Inc.

Condensed Statements of Operations

(in thousands, except for per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Revenues:		
Royalties	$ 68	$ 62
Total revenues	68	62
Costs and expenses:		
Research and development	2,706	2,649
Selling, general and administrative	1,486	1,375
Total operating expenses	4,192	4,024
Loss from operations	(4,124)	(3,962)
Net interest income	36	65
Gain (loss) from change in fair value of derivative financial instruments—warrants	2	(10)
Other (loss) income, net	(3)	2
Net loss	(4,089)	(3,905)
Preferred Stock Dividend	(6)	(274)
Net loss attributable to common stockholders	$ (4,095)	$ (4,179)
Net loss per common share — basic and diluted	$ (0.41)	$ (1.02)
Weighted-average shares outstanding — basic and diluted	9,910	4,087

Trovagene, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 9,277	$ 10,195
Accounts receivable and unbilled receivable	106	204
Prepaid expenses	900	955
Total current assets	10,283	11,354
Property and equipment, net	758	878
Operating lease right-of-use assets	618	697
Other assets	156	158
Total Assets	$ 11,815	$ 13,087
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 599	$ 656
Accrued expenses	3,412	3,260
Operating lease liabilities	870	866
Total current liabilities	4,881	4,782
Derivative financial instruments—warrants	2	4
Operating lease liabilities, net of current portion	650	861
Other Liabilities	139	129
Total Liabilities	5,672	5,776
Stockholders' equity	6,143	7,311
Total liabilities and stockholders' equity	$ 11,815	$ 13,087

Trovagene, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Operating activities		
Net loss	$ (4,089)	$ (3,905)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	119	127
Stock based compensation expense	177	200
Change in fair value of derivative financial instruments—warrants	(2)	10
Release of clinical trial funding commitment	293	70
Changes in operating assets and liabilities	128	138
Net cash used in operating activities	(3,374)	(3,360)
Investing activities:		
Capital Expenditures	—	(5)
Net cash used in investing activities	—	(5)
Financing activities:		
Proceeds from sales of common stock and warrants	1,000	—
Costs related to the clinical trial funding commitment	—	(40)
Proceeds from exercise of warrants	1,456	3,282
Net cash provided by financing activities	2,456	3,242
Net change in cash and cash equivalents	(918)	(123)
Cash and cash equivalents—Beginning of period	10,195	11,453
Cash and cash equivalents—End of period	$ 9,277	$ 11,330