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): **August 11, 2020**

Cardiff Oncology™

Cardiff Oncology, 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**

Trovagene, Inc
(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	CRDF	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 August 11, 2020, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the second quarter ended June 30, 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 Cardiff Oncology, Inc. dated August 11, 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: August 11, 2020

CARDIFF ONCOLOGY, INC.

By: /s/ Mark Erlander
Mark Erlander
Chief Executive Officer

Cardiff Oncology Announces Second Quarter 2020 Results and Highlights

SAN DIEGO (August 11, 2020) – Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage oncology therapeutics company developing drugs to treat cancers with the greatest medical need for new treatment options, including KRAS-mutated colorectal cancer, castrate-resistant prostate cancer and leukemia, today announced company highlights and financial results for the second quarter ended June 30, 2020. The Company is issuing this press release in lieu of conducting a conference call.

“I am very pleased with the progress we made during the second quarter, as we achieved numerous clinical, regulatory and corporate milestones that have driven our sustained growth,” said Dr. Mark Erlander, chief executive officer of Cardiff Oncology. “We announced compelling clinical data demonstrating the safety and efficacy of onvansertib in combination with standard-of-care therapy in KRAS-mutated metastatic colorectal cancer. Additionally, we announced the positive efficacy and safety results of the Phase 1b portion of our trial in relapsed/refractory acute myeloid leukemia and we continue to advance our Phase 2 trial in metastatic castrate-resistant prostate cancer, highlighting the broad commercial opportunity offered by the continued development of onvansertib. Notably, in the second quarter, we secured financing of $25 million from equity investments by biotech-focused institutional investors Acorn Bioventures LP and CAM Capital, the exercise of warrants and funding for clinical study commitments, which have left us well positioned to complete our ongoing clinical trials and continue advancing development of onvansertib."

Program highlights for the quarter ended June 30, 2020 include:

KRAS-mutated Metastatic Colorectal Cancer (mCRC) Program:

Presented data further demonstrating the efficacy of onvansertib in patients with KRAS-mutated mCRC at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting.

Newly announced data from a Phase 1b/2 clinical trial demonstrate the safety and efficacy of onvansertib, an oral and highly selective Polo-like Kinase 1 (PLK1) inhibitor, in combination with FOLFIRI and Avastin® (bevacizumab) in second line KRAS-mutated mCRC patients. These data were featured in a virtual poster presentation at the 2020 ASCO Annual Meeting. Data highlights from the presentation included:

- Onvansertib-FOLFIRI-bevacizumab combination treatment resulted in an 89% overall clinical benefit rate and a 44% (four out of nine patients) objective response rate (ORR) as of the ASCO data cutoff.
- One additional objective response was achieved post ASCO reporting (overall ORR of 45% with five of 11 evaluable patients seeing an objective response).
- Data continues to demonstrate a ten-fold improvement in ORR with onvansertib-FOLFIRI- bevacizumab combination treatment compared to the current standard-of-care.
- Median progression-free survival of >6 months at data cutoff; with six patients remaining on treatment as of the time of the presentation.
- Safety and tolerability demonstrated across all onvansertib dose levels evaluated to-date.

Presented new clinical data showing that onvansertib-FOLFIRI-bevacizumab combination therapy led to consistent tumor regression and durable response across KRAS mutation subtypes in patients with KRAS-mutated mCRC at the American Association for Cancer Research (AACR) annual conference

The newly announced 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 mCRC were featured in Dr. Afsaneh Barzi's virtual oral presentation at the 2020 AACR annual conference. The ongoing Phase 1b/2 trial has enrolled 12 patients with responses seen in seven of eight (88%) evaluable patients to-date: three patients exhibiting a partial response (PR), and four patients with stable disease (SD). Levels of circulating tumor DNA (ctDNA) with KRAS mutations in the blood during treatment are used as a predictive biomarker in the trial, with a decrease to non-detectable levels during the first treatment cycle being indicative of subsequent tumor regression and response.

Announced the U.S. Food and Drug Administration's (FDA) decision to grant Fast Track Designation to onvansertib for second line treatment of KRAS-mutated colorectal cancer

The FDA's decision to grant Fast Track Designation to onvansertib for the second line treatment of KRAS-mutated mCRC, provides us with the opportunity to seek priority review and accelerated approval in this indication. This designation underscores the urgent need for new treatment options for KRAS-mutated mCRC patients and indicates that the FDA concluded that the investigation of onvansertib, in combination with FOLFIRI/bevacizumab, for second line treatment of patients with KRAS-mutated mCRC, met the criteria for a Fast Track development program.

Announced initiation of Expanded Access Program (EAP) for onvansertib in combination with standard-of-care FOLFIRI and bevacizumab for the treatment of second line KRAS-mutated mCRC

Initiation of the EAP provides patients with a pathway to gain access to treatment with onvansertib outside of our clinical trial.

Acute Myeloid Leukemia (AML) Program:

Presented clinical data further demonstrating the efficacy, durability and safety of onvansertib in patients with difficult-to-treat relapsed/refractory AML at the European Hematology Association (EHA) annual conference

Final results of our Phase 1b relapsed/refractory AML study, and positive preliminary data from our Phase 2 relapsed/refractory AML study, were presented as a virtual poster at the 2020 EHA annual conference. Data highlights from the presentation included:

- Phase 1b: Seven out of 21 (33%) evaluable patients achieved an objective response, with five (24%) patients achieving a complete response (CR/CRi).
- Phase 1b: Among the five patients achieving a CR/CRi, one patient proceeded to transplant and three patients remain on treatment with ongoing durable responses of 6, 12 and 15 months.
- Phase 2: Two out of seven (28%) patients completing one cycle of treatment achieved an objective response. One out of seven (14%) had a complete response (CR) and significant decrease in ctDNA, which was found to be highly predictive of clinical response.
- Phase 2: Data indicate that onvansertib in combination with decitabine continues to be a safe and well-tolerated treatment regimen.

Corporate Milestones:

$25.1 million in equity investments, warrant exercises and clinical trial funding commitments

Second quarter equity investments and warrant exercises to fund current clinical programs and operations:

- $13.5 million equity investment from biotech-focused institutional investors Acorn Bioventures LP and CAM Capital. The financing included common stock, Series E preferred stock and warrants.
- $2.5 million equity investment from biotech-focused institutional investor Acorn Bioventures LP. The financing included common stock and warrants.
- $1.1 million equity investment from Lincoln Park Capital Fund LLP. The financing included common stock and warrants.
- $0.8 million private placement by the Board of Directors and Chief Executive Officer. The company sold common stock at market prices.
- $4.9 million in various warrant exercises.

Second quarter clinical trial funding commitments:

- $2.3 million commitment from PoC Capital to fund our Phase 2 clinical trial of onvansertib in KRAS-mutated mCRC. The financing included common stock, Series D preferred stock and warrants.

Company name change to Cardiff Oncology, Inc.

On May 8, 2020, we changed our company name from Trovagene, Inc. to Cardiff Oncology, Inc., and our Nasdaq ticker symbol from 'TROV' to 'CRDF.' The web address for the Cardiff Oncology website is www.cardiffoncology.com.

Appointment of Dr. Mark Erlander as chief executive officer

On May 8, 2020, Mark Erlander, Ph.D., assumed the role of chief executive officer and Thomas Adams, Ph.D., transitioned from chief executive officer and chairman to executive chairman.

Strengthened Board of Directors with the addition of three industry leaders

Shareholders elected three new independent directors to our board of directors; Dr. James Armitage, Dr. Gary Pace and Ms. Lâle White. Each new director brings extensive and relevant experience to the board of Cardiff Oncology.

Second Quarter 2020 Financial Results:

As of June 30, 2020, Cardiff Oncology had approximately $27.8 million in cash and cash equivalents and $2.8 million in clinical trial funding commitments included within stockholders' equity.

Total operating expenses were approximately $4.1 million for the three months ended June 30, 2020, a decrease of $0.2 million from $4.3 million for the same period in 2019. The decrease in operating expenses is attributed to a decrease in costs associated with clinical programs and outside services, partially offset by an increase in stock-based compensation and staff costs.

Net cash used in operating activities in the second quarter of 2020 was $4.3 million, an increase of $0.9 million from $3.4 million for the same period in 2019. The increase is attributed to the net changes in our operating assets and liabilities.

Research and development expenses decreased by approximately $0.3 million to $2.5 million for the three months ended June 30, 2020, from $2.8 million for the same period in 2019. The decrease in research and development expenses was primarily due to lower expenses associated with clinical programs and outside services.

Selling, general and administrative expenses increased by approximately $0.3 million to $1.7 million for the three months ended June 30, 2020 from $1.4 million for the same period in 2019. The increase is primarily due to an increase in stock-based compensation, staff costs and facilities, off-set by a decrease in outside services.

About Cardiff Oncology, Inc.

Cardiff Oncology (formerly Trovagene, Inc.) 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 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.cardiffoncology.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 Cardiff Oncology's expectations, strategy, plans or intentions. These forward-looking statements are based on Cardiff Oncology'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 Cardiff Oncology'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 Cardiff Oncology does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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Cardiff Oncology, Inc.

Condensed Statements of Operations

(in thousands, except for per share amounts)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Royalties	$ 43	$ 37	$ 110	$ 99
Services	—	1	—	1
Total revenues	43	38	110	100
Costs and expenses:				
Research and development	2,476	2,830	5,181	5,479
Selling, general and administrative	1,669	1,428	3,155	2,803
Total operating expenses	4,145	4,258	8,336	8,282
Loss from operations	(4,102)	(4,220)	(8,226)	(8,182)
Interest income	15	70	51	135
Gain (loss) from change in fair value of derivative financial instruments—warrants	(44)	24	(42)	14
Other income (expense), net	6	1	4	3
Net loss	(4,125)	(4,125)	(8,213)	(8,030)
Preferred stock dividend	(6)	(6)	(12)	(12)
Deemed dividend on preferred stock	(3,266)	—	(3,266)	(268)
Net loss attributable to common stockholders	$ (7,397)	$ (4,131)	$ (11,491)	$ (8,310)
Net loss per common share — basic and diluted	$ (0.51)	$ (0.76)	$ (0.94)	$ (1.75)
Weighted-average shares outstanding — basic and diluted	14,492	5,408	12,201	4,751

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 27,755	$ 10,195
Accounts receivable and unbilled receivable	109	204
Prepaid expenses	955	955
Total current assets	28,819	11,354
Property and equipment, net	655	878
Operating lease right-of-use assets	502	697
Other assets	153	158
Total Assets	$ 30,129	$ 13,087
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,155	$ 656
Accrued expenses	2,858	3,260
Note payable	71	—
Operating lease liabilities	878	866
Total current liabilities	4,962	4,782
Derivative financial instruments—warrants	46	4
Note payable, net of current portion	234	—
Operating lease liabilities, net of current portion	430	861
Other Liabilities	73	129
Total Liabilities	5,745	5,776
Stockholders' equity	24,384	7,311
Total liabilities and stockholders' equity	$ 30,129	$ 13,087

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2020	**2019**
Operating activities		
Net loss	$ (8,213)	$ (8,030)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment loss	34	—
Depreciation	234	249
Stock based compensation expense	459	349
Change in fair value of derivative financial instruments—warrants	42	(14)
Release of clinical trial funding commitment	507	311
Changes in operating assets and liabilities	(728)	332
Net cash used in operating activities	(7,665)	(6,803)
Investing activities:		
Capital Expenditures	—	(5)
Net cash used in investing activities	—	(5)
Financing activities:		
Proceeds from sales of common stock, preferred stock and warrants, net of expenses	18,802	2,902
Costs related to the clinical trial funding commitment	(8)	(40)
Proceeds from exercise of warrants, net of expenses	6,126	3,284
Borrowings under long-term debt	305	—
Net cash provided by financing activities	25,225	6,146
Net change in cash and cash equivalents	17,560	(662)
Cash and cash equivalents—Beginning of period	10,195	11,453
Cash and cash equivalents—End of period	$ 27,755	$ 10,791