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 5, 2020**

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:

☐ 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 Conditions.

On November 5, 2020, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the third quarter ended September 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 November 5, 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: November 5, 2020

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology™

Cardiff Oncology Announces Third Quarter 2020 Results and Highlights

SAN DIEGO (November 5, 2020) – Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company developing drugs to treat cancers with the greatest medical need for new treatment options, including KRAS-mutated colorectal cancer, castration-resistant prostate cancer and leukemia, today announced company highlights and financial results for the third quarter ended September 30, 2020. The Company is issuing this press release in lieu of conducting a conference call.

“Cardiff Oncology has seen robust growth over the past few months, which has been driven primarily by clinical data sets demonstrating safety and efficacy of onvansertib in solid tumor indications,” said Dr. Mark Erlander, chief executive officer of Cardiff Oncology. “Data from our lead KRAS-mutated metastatic colorectal cancer (mCRC) program presented at the European Society for Medical Oncology (ESMO) conference, shows that the addition of onvansertib to standard-of-care therapy has led to durable responses and a significant improvement in the objective response rate (ORR) versus historical ORR’s of standard-of-care alone, highlighting onvansertib’s ability to address a critical unmet need in second-line treatment. We have also seen progress in our metastatic castration-resistant prostate cancer (mCRPC) program, presenting positive biomarker and efficacy data demonstrating onvansertib’s ability to overcome Zytiga® resistance across known androgen receptor resistance mechanisms, at the Prostate Cancer Foundation (PCF) Scientific Retreat."

Dr. Erlander continued, “alongside our recent clinical achievements, we also executed on a major corporate milestone in early October with the Company closing an underwritten public offering of its common stock for gross proceeds of approximately $100 million. These funds will enable us to continue executing on our current programs and also initiate new clinical programs in other cancer indications.”

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

KRAS-mutated Metastatic Colorectal Cancer (mCRC) Program:

Presented clinical data at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 confirming the efficacy of onvansertib and the durability of response in second line KRAS-mutated mCRC patients

Newly announced data from a Phase 1b/2 clinical trial evaluating onvansertib in combination with FOLFIRI/bevacizumab in second line KRAS-mutated mCRC were featured in an electronic poster at the ESMO Virtual Congress 2020. These data further demonstrate the safety, efficacy and durability of response of onvansertib in combination with FOLFIRI/bevacizumab and suggest that changes in plasma KRAS mutation levels may serve as a predictive biomarker of patient response. Data highlights from the presentation included:

- 10 of 11 (91%) patients achieved disease control (SD – stable disease plus PR – partial response), with only 1 patient progressing in <6 months while on treatment
- 5 of 11 (45%) patients achieved a PR; 4 patients had a confirmed PR with 1 patient going on to curative surgery; 1 patient with an initial PR went off study prior to confirmatory scan due to a non-treatment related event

- 8 of 11 (73%) patients demonstrated durable response ranging from 6 to >12 months, and 4 patients remain on treatment
- Patients achieving a PR showed the greatest decreases in plasma KRAS mutation levels (ranging from -78% to -100%) after one cycle of therapy
- Data demonstrated that onvansertib in combination with FOLFIRI/bevacizumab is safe and well tolerated

Hosted a Key Opinion Leader (KOL) call discussing KRAS-mutated colorectal cancer and highlighting data from the onvansertib Phase 1b/2 trial

The call featured KOLs Afsaneh Barzi, M.D., Ph.D. (City of Hope Comprehensive Cancer Center) and Heinz-Josef Lenz, M.D., FACP (USC Norris Comprehensive Cancer Center). In addition to a discussion of the latest data from the Phase 1b/2 trial of onvansertib in KRAS-mutated mCRC, the call also included an overview of the history of KRAS in clinical practice, the challenges of drug development and targeting of KRAS and the value of KRAS as a biomarker for patient selection and predicting response to treatment. You may access a replay of the event by clicking here.

Highlights for the period subsequent to the quarter end include:

Corporate Milestones:

Strengthened balance sheet with gross proceeds of approximately $100 million in offering of common stock

On October 2nd, Cardiff Oncology closed an underwritten offering of 6,500,000 shares of its common stock at a public offering price of $13.50 per share, before deducting underwriter discounts and commissions and estimated offering expenses. The underwriters also exercised an option to purchase an additional 975,000 shares at the public offering price (less underwriting discounts and commissions). Cardiff Oncology intends to use the net proceeds from this offering for clinical development of onvansertib, working capital and for other general corporate purposes.

Clinical Milestones:

Metastatic Castration Resistant Prostate Cancer (mCRPC) Program:

Presented positive efficacy and biomarker data from Phase 2 mCRPC trial demonstrating ability of onvansertib to overcome Zytiga® resistance at the 27th Prostate Cancer Foundation (PCF) Scientific Retreat
An electronic poster presented at the PCF retreat featured new data and analyses related to an ongoing Phase 2 trial evaluating onvansertib in combination with Zytiga® (abiraterone acetate) and prednisone in mCRPC patients. The poster included efficacy data demonstrating success in achieving the primary endpoint of disease control in patients showing initial resistance to Zytiga®; safety across three different dose and dosing schedules, as well as the potential clinical benefit for patients with the basal molecular tumor subtype. Additional highlights from the presentation included:

- 8 of 26 (31%) evaluable patients achieved the primary endpoint of disease control (defined by a lack of prostate specific antigen progression) after 12 weeks of treatment
- 14 of 26 (54%) evaluable patients had stable disease (SD) after 12 weeks of treatment
- 8 of 26 (31%) evaluable patients had a durable SD (>7 months)

- Of 8 patients harboring androgen receptor alterations associated with Zytiga® resistance, 3 achieved disease control at 12 weeks, 4 had SD at 12 weeks and 3 had a durable SD (>7 months)
- Median time on treatment was 9.2 months for patients with a decrease in circulating tumor cell (CTC) count (n=5) vs. 4.9 months for patients with a CTC increase (n=5)
- Genetic analyses identified a gene signature (biomarker) associated with onvansertib and Zytiga® synergy in prostate cancer cells that is significantly enriched in the basal molecular subtype of prostate cancer patients
- Data shows that the combination of onvansertib and Zytiga® is safe across all evaluated dosing schedules

Third Quarter 2020 Financial Results:

As of September 30, 2020, Cardiff Oncology had approximately $36.4 million in cash and cash equivalents.

Total operating expenses were approximately $4.5 million for the three months ended September 30, 2020, an increase of $0.2 million from $4.3 million for the same period in 2019. The increase in operating expenses is attributed to an increase in costs associated with clinical programs and outside services, stock-based compensation and staff costs.

Net cash used in operating activities in the third quarter of 2020 was $3.5 million, an increase of $0.3 million from $3.2 million for the same period in 2019. The increase is attributed to increases in operating expenses and the net changes in our operating assets and liabilities.

Research and development expenses increased by approximately $0.1 million to $2.9 million for the three months ended September 30, 2020, from $2.8 million for the same period in 2019. The increase in research and development expenses was primarily due to expenses associated with clinical programs and outside services.

Selling, general and administrative expenses increased by approximately $0.2 million to $1.6 million for the three months ended September 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; 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Royalties	$ 136	$ 52	$ 247	$ 151
Services	—	—	—	1
Total revenues	136	52	247	152
Costs and expenses:				
Research and development	2,855	2,819	8,036	8,298
Selling, general and administrative	1,644	1,440	4,800	4,243
Total operating expenses	4,499	4,259	12,836	12,541
Loss from operations	(4,363)	(4,207)	(12,589)	(12,389)
Interest income	16	54	67	188
Gain (loss) from change in fair value of derivative financial instruments—warrants	(144)	13	(186)	27
Other income (expense), net	(6)	(1)	(2)	2
Net loss	(4,497)	(4,141)	(12,710)	(12,172)
Preferred stock dividend	(6)	(6)	(18)	(18)
Deemed dividend on preferred stock	—	—	(3,266)	(268)
Net loss attributable to common stockholders	$ (4,503)	$ (4,147)	$ (15,994)	$ (12,458)
Net loss per common share — basic and diluted	$ (0.19)	$ (0.69)	$ (1.00)	$ (2.40)
Weighted-average shares outstanding — basic and diluted	23,341	6,025	15,942	5,180

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 36,405	$ 10,195
Accounts receivable and unbilled receivable	205	204
Prepaid expenses and other current assets	1,579	955
Total current assets	38,189	11,354
Property and equipment, net	683	878
Operating lease right-of-use assets	423	697
Other assets	156	158
Total Assets	$ 39,451	$ 13,087
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 610	$ 656
Accrued expenses	3,643	3,260
Note payable	305	—
Operating lease liabilities	884	866
Total current liabilities	5,442	4,782
Derivative financial instruments—warrants	190	4
Operating lease liabilities, net of current portion	207	861
Other Liabilities	89	129
Total Liabilities	5,928	5,776
Stockholders' equity	33,523	7,311
Total liabilities and stockholders' equity	$ 39,451	$ 13,087

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Operating activities		
Net loss	$ (12,710)	$ (12,172)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment loss	34	—
Depreciation	349	373
Stock based compensation expense	821	615
Change in fair value of derivative financial instruments—warrants	186	(27)
Release of clinical trial funding commitment	868	509
Changes in operating assets and liabilities	(739)	712
Net cash used in operating activities	(11,191)	(9,990)
Investing activities:		
Capital Expenditures	(154)	(68)
Net cash used in investing activities	(154)	(68)
Financing activities:		
Proceeds from sales of common stock, preferred stock and warrants, net of expenses	18,279	4,386
Costs related to the clinical trial funding commitment	(8)	(40)
Proceeds from exercise of options	7	—
Proceeds from exercise of warrants, net of expenses	18,972	3,291
Borrowings under note payable	305	—
Net cash provided by financing activities	37,555	7,637
Net change in cash and cash equivalents	26,210	(2,421)
Cash and cash equivalents—Beginning of period	10,195	11,453
Cash and cash equivalents—End of period	$ 36,405	$ 9,032