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): **October 20, 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 8.01 Other Events.

On October 20, 2020, Cardiff Oncology, Inc. issued a press release announcing that new data and analyses related to its ongoing Phase 2 trial of onvansertib in metastatic castration-resistant prostate cancer (mCRPC) patients were featured in an electronic poster at the 27th Annual Prostate Cancer Foundation (PCF) Scientific Retreat. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1	Press Release of Cardiff Oncology, Inc. dated October 20, 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: October 20, 2020

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Presents Positive Efficacy and Biomarker Data from mCRPC Trial Demonstrating Ability of Onvansertib to Overcome Zytiga® Resistance

- Trial on track to meet prespecified criteria for success on its primary endpoint, with 31% (8/26) disease control rate in evaluable patients in cohorts A and B. Patients eligible for the trial have two consecutive rises in PSA levels indicating initial resistance to abiraterone (Zytiga®)
- Safety demonstrated across all three dose/dose scheduling cohorts, including cohort C with onvansertib dosed over a longer period of time than cohorts A and B (onvansertib on Days 1 – 14 in a 21-day cycle); 2 of 3 patients treated to-date in cohort C achieved primary efficacy endpoint at 12 weeks
- Recent collaborative studies with Massachusetts Institute of Technology (MIT) and Decipher Biosciences suggest that prostate cancer patients with the clinically defined basal molecular tumor subtype may be more likely to respond to onvansertib being added to ongoing abiraterone therapy

SAN DIEGO (October 20, 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 that new data and analyses related to its ongoing Phase 2 trial of onvansertib in metastatic castration-resistant prostate cancer (mCRPC) patients were featured in an electronic poster at the 27th Annual Prostate Cancer Foundation (PCF) Scientific Retreat. The poster includes efficacy data demonstrating success in achieving the primary endpoint of disease control in patients showing initial resistance to Zytiga® (abiraterone); safety across three different dose and dosing schedules, as well as the potential clinical benefit for patients with the basal molecular tumor subtype.

"There is a pressing unmet need for therapies that can address resistance to abiraterone and other androgen receptor signaling inhibitors (ARSi), in mCRPC," said David Einstein, M.D., attending physician at Beth Israel Deaconess Medical Center and principal investigator of the onvansertib Phase 2 trial. "Data presented at the PCF retreat demonstrate the potential of onvansertib to address this need, as we are seeing clinically meaningful rates of disease control, some quite durable, in patients with known mechanisms of ARSi resistance."

Mike Yaffe, M.D., Ph.D., David H. Koch Professor of Science and Professor of Biology and Biological Engineering at MIT, added, "We continue to be excited about the collaboration with Cardiff Oncology and the work we have been conducting to unlock the mechanism of synergy between PLK1 inhibition and abiraterone, which we have previously shown to be independent of AR signaling. We have now identified a specific set of genes related to cell division pathways that can be used to predict which cancer cells will specifically show a synergistic anti-tumor response to treatment with abiraterone in combination with a PLK1 inhibitor. Intriguingly, this set of genes is most correlated with the known molecular basal subtype which suggests that

prostate cancer patients with this specific tumor subtype may be more likely to respond to onvansertib-abiraterone combination therapy."

"We are very pleased with the progress and results of the trial to date," said Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology. "In particular, we are encouraged by the identification of a biomarker that could readily select for abiraterone-resistant patients who are most likely to benefit from the addition of onvansertib to their regimen."

Highlights of the PCF Poster Presentation:

Efficacy:

- 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 durable SD (>7 months)
- Of 8 patients harboring AR alterations associated with Zytiga® resistance, 3 achieved disease control at 12 weeks, 4 had SD at 12 weeks and 3 had durable SD (>7 months)

Biomarker Analyses:

- Identification of a gene signature (biomarker) associated with onvansertib and abiraterone synergy in prostate cancer cells that is significantly enriched in the basal molecular subtype of prostate cancer patients

Safety:

- The trial's safety lead-in is complete across Arm A (24 mg/m^2 onvansertib), Arm B (18 mg/m^2 onvansertib) and Arm C (12 mg/m^2 onvansertib)
- Data show that the combination of onvansertib and abiraterone (Zytiga®) is safe across three different dosing schedules

The poster presented as part of the 27th Annual PCF Scientific Retreat is available on the "Scientific Presentations" section of the Cardiff Oncology website at https://cardiffoncology.com/scientific-presentations/.

About the Phase 2 Trial of Onvansertib in Metastatic Castration-Resistant Prostate Cancer

This trial is a Phase 2 open-label study of onvansertib in combination with Zytiga® (abiraterone) and prednisone, all administered orally, in patients with metastatic castration-resistant prostate cancer showing signs of early progressive disease (demonstrated by two rising prostate-specific antigen values separated by at least one week with no or minimal symptoms) while on Zytiga®/prednisone therapy. The primary efficacy endpoint is the proportion of patients achieving disease control after 12 weeks of study treatment, as defined by a lack of prostate specific antigen (PSA), radiographic, or symptomatic progression. The trial is being conducted by Beth Israel Deaconess Medical Center (BIDMC), Dana-Farber Cancer Institute (Dana-Farber), and Massachusetts General Hospital Cancer Center (MGH). David Einstein, MD, Genitourinary Oncology Program at BIDMC, is the principal investigator for the trial. For more information on the trial, please visit https://www.clinicaltrials.gov/ct2/show/NCT03414034.

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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