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 28, 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 May 28, 2020, Cardiff Oncology, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to onvansertib, its oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor, for the second-line treatment of patients with KRAS-mutated metastatic colorectal cancer (mCRC). 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 May 28, 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 28, 2020

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Announces Fast Track Designation Granted by the FDA to Onvansertib for Second-Line Treatment of KRAS-Mutated Colorectal Cancer

- ***The U.S. Food and Drug Administration reviewed the Company's request for Fast Track designation and concluded that investigation of onvansertib, in combination with FOLFIRI/bevacizumab, for second-line treatment of patients with KRAS-mutated metastatic colorectal cancer meets the criteria for a Fast Track development program***

- ***Fast Track designation for onvansertib in KRAS-mutated metastatic colorectal cancer underscores the urgent need for new treatment options for these patients***

SAN DIEGO (May 28, 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, Zytiga®-resistant prostate cancer and leukemia, today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to onvansertib, its oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor, for the second-line treatment of patients with KRAS-mutated metastatic colorectal cancer (mCRC).

"We are very pleased with the FDA's decision to grant Fast Track designation for development of onvansertib to treat patients with KRAS-mutated mCRC," said Dr. Mark Erlander, Chief Executive Officer of Cardiff Oncology. "This designation is a significant validation of not only our onvansertib clinical program, which is now eligible for priority review and accelerated approval, but it also signifies recognition of the medical need for new effective treatment options. The efficacy of current second-line therapy in terms of response and survival prolongation remains very limited, particularly in the KRAS-mutated population, and we are confident that onvansertib, in combination with FOLFIRI/bevacizumab, represents a promising new treatment option."

Fast Track is a designation granted by the FDA that is intended to facilitate development and expedite review of drugs to address an unmet medical need in the treatment of a serious life-threatening condition, and for which nonclinical or clinical data has demonstrated the potential of the drug to address this medical need.

A drug that receives Fast track Designation is eligible for some, or all, of the following:

- Eligibility for accelerated approval and priority review, if relevant criteria are met
- Rolling review, enabling Cardiff Oncology to submit completed sections of its New Drug Application (NDA) for review by the FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed (NDA review usually does not begin until the Company has submitted the entire NDA to the FDA)
- More frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data to support drug approval
- More frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers

About the Phase 1b/2 Clinical Trial of Onvansertib in KRAS-Mutated mCRC

In this open-label, Phase 1b/2 trial, onvansertib in combination with standard-of-care FOLFIRI and Avastin® (bevacizumab) is being evaluated for safety and efficacy for second-line treatment of patients with KRAS-mutated mCRC. The trial, *A Phase 1b/2 Study of Onvansertib (PCM-075) in Combination with FOLFIRI and Bevacizumab for Second□Line Treatment of Metastatic Colorectal Cancer in Patients with a KRAS Mutation,* will enroll up to 44 patients with a KRAS mutation and histologically confirmed metastatic and unresectable disease. In addition, patients must have failed treatment or be intolerant of FOLFOX (fluoropyrimidine and oxaliplatin) with or without bevacizumab. The trial is being conducted at two prestigious cancer centers: USC Norris Comprehensive Cancer Center and The Mayo Clinic Arizona.

About Onvansertib

Onvansertib is a first-in-class, third-generation, oral and highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK1) enzyme, which is over-expressed in multiple cancers including leukemias, lymphomas and solid tumors. Onvansertib targets the PLK1 isoform only (not PLK2 or PLK3), is orally administered and has a 24-hour half-life with only mild-to-moderate side effects reported. Cardiff Oncology believes that targeting only PLK1 and having a favorable safety and tolerability profile, along with an improved dose/scheduling regimen will significantly improve on the outcome observed in previous studies with a former panPLK inhibitor in AML.

Onvansertib has demonstrated synergy in preclinical studies with numerous chemotherapies and targeted therapeutics used to treat leukemias, lymphomas and solid tumor cancers, including irinotecan, FLT3 and HDAC inhibitors, taxanes and cytotoxins. Cardiff Oncology believes the combination of onvansertib with other compounds has the potential to improve clinical efficacy in acute myeloid leukemia (AML), metastatic castration-resistant prostate cancer (mCRPC), non-Hodgkin lymphoma (NHL), colorectal cancer and triple-negative breast cancer (TNBC), as well as other types of cancer.

Cardiff Oncology has three ongoing clinical trials of onvansertib: A Phase 2 trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with mCRPC who are showing signs of early progressive disease (rise in PSA but minimally symptomatic or asymptomatic) while currently receiving Zytiga® (NCT03414034); a Phase 1b/2 Study of onvansertib in combination with FOLFIRI and Avastin® for second-line treatment in patients with mCRC with a KRAS mutation (NCT03829410; and a Phase 2 clinical trial of onvansertib in combination with decitabine in patients with relapsed or refractory AML (NCT03303339).

Cardiff Oncology licensed onvansertib (also known as NMS-1286937 and PCM-075) from Nerviano Medical Sciences (NMS), the largest oncology-focused research and development company in Italy, and a leader in protein kinase drug development. NMS has an excellent track record of licensing innovative drugs to pharma/biotech companies, including Array (recently acquired by Pfizer), Ignyta (acquired by Roche) and Genentech.

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 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.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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