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): **January 26, 2021**

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**

(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 January 26, 2021, Cardiff Oncology, Inc. issued a press release today announced that it has received a Study May Proceed letter from the U.S. Food and Drug Administration to begin a Phase 2 clinical trial of onvansertib in metastatic pancreatic ductal adenocarcinoma (PDAC). 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 January 26, 2021.

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: January 26, 2021

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Receives “Study May Proceed” from FDA to Initiate Phase 2 Trial of Onvansertib in Metastatic Pancreatic Ductal Adenocarcinoma (PDAC)

- Trial will evaluate the safety and efficacy of onvansertib in combination with standard-of-care for second-line treatment of patients with metastatic PDAC who have failed first line treatment with a gemcitabine-based chemotherapy regimen

SAN DIEGO (January 26, 2021) – 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 it has received a Study May Proceed letter from the U.S. Food and Drug Administration (FDA) to begin a Phase 2 clinical trial of onvansertib in metastatic pancreatic ductal adenocarcinoma (PDAC).

This Phase 2 clinical trial is designed to assess the safety and preliminary efficacy of onvansertib in combination with nanoliposomal irinotecan (Onyvide®), 5-FU and leucovorin as a second-line treatment in patients with metastatic PDAC who have failed first-line gemcitabine-based therapy. The trial is expected to enroll approximately 40 patients across six sites in the U.S. including the three Mayo Clinic Cancer Centers (Arizona, Minnesota and Florida), Emory University, Kansas University Medical Center and Inova Schar Cancer Institute.

“We are excited about the potential of onvansertib in PDAC and originally proposed this trial to Cardiff Oncology because of the results we are seeing in patients treated in our ongoing Phase 1b/2 trial in KRAS-mutated mCRC, which is also evaluating onvansertib in combination with nanoliposomal irinotecan and 5-FU,” said Dr. Daniel H. Ahn, medical oncologist at the Mayo Clinic Cancer Center (Arizona), principal investigator for the Phase 2 PDAC trial and lead investigator for the Phase 1b/2 KRAS-mutated metastatic colorectal cancer (mCRC) trial. “These data show promising response rates with impressive durability across several KRAS variants following treatment. We believe these clinical benefits can be extended to PDAC, as approximately 95% have a KRAS mutation and onvansertib inhibits the proliferation and survival of KRAS-mutated tumor cells. We are looking forward to starting this important trial and providing our PDAC patients with a new second-line therapy with the potential to change the course of this devastating cancer.”

“The FDA’s clearance of our Investigational New Drug application for a Phase 2 clinical study in patients with metastatic pancreatic cancer is an important milestone for onvansertib and represents a significant step forward in our development of a potential new treatment in an indication where current therapeutic options are limited and patient prognosis is poor,” said Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology. “By parlaying the known synergy between onvansertib and standard-of-care nanoliposomal irinotecan and 5-FU therapy, we believe we can offer a promising new treatment option that has the potential to improve patient outcomes.”

About the Phase 2 Trial of Onvansertib in Metastatic PDAC

This trial is a multi-center, open-label, single-arm study designed to assess the safety and efficacy of onvansertib in combination with nanoliposomal irinotecan (Onyvide®), leucovorin,

and 5-FU as a second-line treatment in patients with metastatic PDAC. The trial is expected to enroll approximately 40 patients with histologically confirmed measurable and metastatic PDAC who have failed treatment with one prior line of gemcitabine-based chemotherapy. Patients will receive nanoliposomal irinotecan, leucovorin, and 5-FU on Day 1 of 14-day cycles, plus 12 mg/m^2 onvansertib on Days 1-10, or 15 mg/m^2 onvansertib on Days 1-5 of each 14-day cycle. The study will be conducted at six clinical trial sites across the U.S.: Mayo Clinic (Arizona, Minnesota, Florida), Emory University, Kansas University Medical Center and Inova Schar Cancer Institute. The primary endpoint will be overall response rate (ORR) by Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1). Key secondary and exploratory endpoints include duration of response, median overall survival, ORR in patients receiving greater than two treatment cycles, disease control rate (defined as complete response, partial response or stable disease by RECIST v1.1 over the entire treatment period), and assessment of KRAS allelic burden in liquid biopsies as measured by circulating tumor DNA (ctDNA).

About Cardiff Oncology, Inc.

Cardiff Oncology 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 clinical programs that have demonstrated the safety and efficacy of onvansertib: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® (bevacizumab) 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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