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): **February 11, 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:

☐ 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 8.01 Other Events.

On February 11, 2021, Cardiff Oncology, Inc. issued a press release announcing that updated data from its Phase 2 metastatic castration-resistant prostate cancer (mCRPC) trial were featured in a virtual oral poster presentation at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO-GU). 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 February 11, 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: February 11, 2021

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Presents Phase 2 mCRPC Trial Data Showing a Two-Fold Increase in Efficacy with an Optimized Onvansertib Dosing Schedule

- Two-fold increase (29% to 63%) in disease control rate at 12 weeks (the trial's primary efficacy endpoint) seen in patients receiving onvansertib for 14 days vs. 5 days in a 21-day cycle
- 75% (6/8) of evaluable patients in the optimized dosing cohort had stable disease upon radiographic scan at 12 weeks
- All patients in the optimized dosing cohort achieving the primary efficacy endpoint remain on treatment
- Trial on track to meet prespecified criteria for success on its primary efficacy endpoint, with a 35% disease control rate at 12 weeks in evaluable patients across all three cohorts. Patients eligible for the trial have two consecutive rises in PSA levels, indicating initial resistance to Zytiga® (abiraterone).

SAN DIEGO (February 11, 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, pancreatic cancer, castrate-resistant prostate cancer and leukemias, today announced that updated data from its Phase 2 metastatic castrate-resistant prostate cancer (mCRPC) trial were featured in a virtual oral poster presentation at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO-GU). The ongoing Phase 2 trial evaluates the all-oral combination of onvansertib, abiraterone and prednisone in patients showing initial abiraterone resistance, as defined by two consecutive rises in prostate-specific antigen (PSA) levels.

Newly presented data from the Phase 2 mCRPC trial showed that increasing the number of days of treatment with onvansertib from 5 to 14 in a 21-day cycle was associated with a greater than two-fold increase (29% to 63%) in disease control rate (DCR; defined by lack of PSA progression) at 12 weeks, the trial's primary efficacy endpoint. Six of eight (75%) evaluable patients receiving onvansertib for 14 of 21 days per cycle had stable disease upon radiographic scan at 12 weeks and five of these patients remain on treatment to-date. Across all cohorts, the DCR at 12 weeks is 35% (13/37), indicating the trial is on track to meet the stated criteria for success on its primary efficacy endpoint (30% DCR at 12 weeks).

"The preliminary data presented at ASCO-GU support a clinically meaningful onvansertib exposure effect," said David Einstein, M.D., attending physician at Beth Israel Deaconess Medical Center and principal investigator of the onvansertib mCRPC Phase 2 trial. "In the first eight patients treated to-date on Arm C, we are excited to see an increase in DCR with greater time on onvansertib, without excessive toxicity. Together with the clinically meaningful rates of disease control, and duration of disease control, we are seeing across all cohorts, these data demonstrate onvansertib's potential to address a critical unmet need for patients with abiraterone-resistant mCRPC."

“As data from this trial continue to emerge, we are very pleased to see increased efficacy with an optimized dosing schedule that is both well tolerated and increases the number of days a patient receives onvansertib in combination with abiraterone by nearly 3-fold” said Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology. “These data suggest that the synergy demonstrated between onvansertib and abiraterone in pre-clinical models is being observed clinically. The trial’s biomarker analyses are also promising, as the identification of mutations associated with response to the combination of onvansertib and abiraterone may enable more efficient design of future clinical studies and the identification of patients most likely to benefit from this combination.”

Key data and conclusions from the ASCO-GU presentation include:

Efficacy:

- The optimized dosing schedule of cohort C shows a greater than two-fold improvement in disease control rate compared to cohorts A and B
  - 63% (5/8) of cohort C patients achieved the primary efficacy endpoint compared to 29% (5/17) and 25% (3/12) of cohort A and B patients, respectively
- 75% (6/8) of evaluable patients in cohort C had radiographic SD at 12 weeks, compared to 53% (9/17) in cohort A, 42% (5/12) in cohort B and 54% (20/37) across all cohorts
- All cohort C patients achieving the primary efficacy endpoint remain on treatment
- 35% (13/37) of evaluable patients across all cohorts (A-C) achieved the primary efficacy endpoint of disease control at 12 weeks
- Efficacy was observed in patients harboring androgen receptor (AR) alterations associated with abiraterone resistance across all 3 arms

Biomarker:

- Circulating tumor DNA (ctDNA) analysis revealed differences in baseline genomic profiles of patients achieving SD at 12 weeks vs. those progressing at or before 12 weeks
- Mutations present exclusively in patients with SD at 12 weeks were associated with cell cycle and DNA repair pathways that may result in increased efficacy of the onvansertib-abiraterone combination

Safety:

- Data show that the combination of onvansertib and abiraterone is well tolerated across the three different dosing schedules of cohorts A-C:
  - Cohort A: 24 mg/m^2 onvansertib on Days 1-5 of 21-day cycles, plus abiraterone and prednisone beginning on Day 1 and continuing uninterrupted throughout each cycle
  - Cohort B: 18 mg/m^2 onvansertib on Days 1-5 of 14-day cycles, plus abiraterone and prednisone beginning on Day 1 and continuing uninterrupted throughout each cycle

- Cohort C: 12 mg/m^2 onvansertib on Days 1-14 of 21-day cycles, plus abiraterone and prednisone beginning on Day 1 and continuing uninterrupted throughout each cycle

The virtual poster, *A Phase 2 Study of the Polo-like Kinase 1 (PLK1) Inhibitor Onvansertib in Combination with Abiraterone and Prednisone in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC)*, 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 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, M.D., 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 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). A new Phase 2 trial of onvansertib in combination with nanoliposomal irinotecan, leucovorin and fluorouracil for the second-line treatment of patients with metastatic pancreatic ductal adenocarcinoma (PDAC) is planned for initiation in the first half of 2021. 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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