
**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): **March 10, 2021**



Cardiff Oncology, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-35558
(Commission File Number)

27-2004382
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 March 10, 2021, Cardiff Oncology, Inc. (the “Company”) issued a press release announcing the publication of two abstracts that will be presented as electronic posters during Week 1 of the American Association for Cancer Research (AACR) Annual Meeting 2021, taking place virtually from April 10-15, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

On March 11, 2021, the Company announced that Dr. Mark Erlander, chief executive officer of the Company, will present and participate in one-on-one investor meetings at the Oppenheimer 31st Annual Healthcare Conference taking place March 16-18, 2021. A copy of the press release is furnished as Exhibit 99.2 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 [Press Release of Cardiff Oncology, Inc. dated March 10, 2021.](#)

99.2 [Press Release of Cardiff Oncology, Inc. dated March 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: March 11, 2021

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Announces Upcoming Presentations at the AACR Annual Meeting 2021

SAN DIEGO (March 10, 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 the publication of two abstracts that will be presented as electronic posters during Week 1 of the American Association for Cancer Research (AACR) Annual Meeting 2021, taking place virtually from April 10-15, 2021.

Details on the electronic posters and corresponding abstracts are shown below.

Title: Expanded access program of the PLK1 inhibitor onvansertib for treatment of patients with KRAS-mutant metastatic colorectal cancer

Session Type: E-Poster Session

Session Category: Clinical Research (Excluding Trials)

Session Title: Clinical Outcomes Research

Abstract Number: 425

This abstract includes findings from Cardiff Oncology's Expanded Access Program (EAP) for onvansertib in KRAS-mutated metastatic colorectal cancer (mCRC). The findings show that of the 13 patients with a KRAS mutation detected in circulating tumor DNA (ctDNA) at baseline, 8 had a decrease of greater than 50% in KRAS mutant allelic frequency (MAF) following two treatment cycles of onvansertib (15 mg/m², Days 1 to 5 of a 14-day cycle) in combination with FOLFIRI and bevacizumab (Day 1 of each cycle). Additional observations regarding clinical benefit and correlations between KRAS MAF and treatment response will be featured as part of the upcoming electronic poster presentation at the AACR annual meeting.

Title: The selective polo-like kinase (Plk1) inhibitor onvansertib and the antiandrogen abiraterone synergistically kill cancer cells through disruption of mitosis independently of androgen receptor signaling

Session Type: E-Poster Session

Session Category: Experimental and Molecular Therapeutics

Session Title: Cell Cycle Mechanisms of Anticancer Drug Action

Abstract Number: 973

This abstract describes preclinical studies that aim to identify the mechanisms driving onvansertib-abiraterone synergy by treating prostate cancer cell lines showing, or not showing, synergy between these drugs with vehicle, abiraterone, enzalutamide, or onvansertib prior to RNA sequencing and Gene Set Variation Analysis (GSVA). In synergistic cells, a group of mitosis and mitotic spindle related gene sets were significantly upregulated by both abiraterone and onvansertib. These gene sets were not upregulated in non-synergistic cells, or by enzalutamide, indicating that abiraterone may target mitosis related genes or processes in an androgen receptor-independent manner. Data also suggested that baseline differences in mitotic arrest and spindle assembly checkpoint dependent cell death pathways may be predictive of synergy and patient response to the onvansertib-abiraterone combination. This hypothesis is currently

being evaluated in an ongoing Phase 2 trial evaluating the all-oral regimen of onvansertib, abiraterone and prednisone in metastatic castrate-resistant prostate cancer patients showing initial abiraterone resistance.

The full texts of the published abstracts are currently available on the AACR Annual Meeting 2021 website. The corresponding posters will be available for on-demand viewing on the AACR Annual Meeting 2021 e-poster website starting at 8:30 am ET on April 10, 2021 and will also be posted to the "Scientific Presentations" section of the Cardiff Oncology website at <https://cardiffoncology.com/scientific-presentations/>.

About the Phase 2 Trial of Onvansertib in Metastatic Castrate-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 the Expanded Access Program (EAP) for Onvansertib in KRAS-mutated mCRC

Sometimes called "compassionate use", expanded access is a potential pathway for a patient with a serious or life-threatening disease to gain access to an investigational drug for treatment outside of a clinical trial, particularly when no comparable or satisfactory alternative therapy options are available. The Cardiff Oncology EAP in KRAS-mutated mCRC is using the same combination treatment regimen (onvansertib 15 mg/m² + FOLFIRI/bevacizumab) and dosing schedule as the ongoing Phase 1b/2 clinical trial and is intended for patients that have progressed on prior therapy and do not meet the eligibility criteria for enrollment in the clinical trial. For more information on the expanded access program, please visit <https://clinicaltrials.gov/ct2/show/NCT04446793>.

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>.

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Cardiff Oncology to Present at the Oppenheimer 31st Annual Healthcare Conference

SAN DIEGO (March 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 Dr. Mark Erlander, chief executive officer of Cardiff Oncology, will present and participate in one-on-one investor meetings at the Oppenheimer 31st Annual Healthcare Conference taking place March 16-18, 2021.

Presentation details can be found below.

Date: Thursday, March 18, 2021
Time: 11:20 AM – 11:50 AM ET
Webcast Link: <https://wsw.com/webcast/oppenheimer9/crdf/2687179>

A replay of the presentation will be available by visiting the "[Events](#)" section of the Cardiff Oncology website after the conclusion of the presentation and will be archived on the Company website for 90 days.

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