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): **December 6, 2020**

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 December 6, 2020, Cardiff Oncology, Inc. (the "Company") issued a press release announcing the presentation of updated data from its Phase 1b/2 study in relapsed/refractory acute myeloid leukemia (AML). The data were presented as a virtual oral poster presentation at the 62nd American Society of Hematology (ASH) Annual Meeting. 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 December 6, 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: December 6, 2020

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Presents Data at ASH Demonstrating the Safety and Anti-Leukemic Activity of Onvansertib in Patients with Relapsed/Refractory AML

SAN DIEGO (December 6, 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 the presentation of updated data from its Phase 1b/2 study in relapsed/refractory acute myeloid leukemia (AML). The data were presented as a virtual oral poster presentation at the 62nd American Society of Hematology (ASH) Annual Meeting.

The presentation highlighted the safety, tolerability and anti-leukemic activity of onvansertib in combination with decitabine in patients with difficult-to-treat relapsed/refractory AML. Nine of 45 (20%) patients achieved a complete remission with or without hematologic count recovery (CR/CRi – 5 in Phase 1b and 4 in Phase 2); 55% of responders had a mutation in a splicing factor.
Two patients proceeded to transplant following CR and four patients remain on treatment with duration of response of 9, 10, 17 and 20 months, respectively. Together with data demonstrating the safety and tolerability of the combination therapy, these findings highlight onvansertib's potential to address critical unmet needs in hematologic malignancies.

"The data generated from this ongoing trial are encouraging, particularly considering the very poor prognosis of the relapsed/refractory AML patient population, in whom the median overall survival is generally only a few months," said Dr. Mark Erlander, chief executive officer of Cardiff Oncology. "We believe the over-representation of the splicing factor mutations in patients who achieved a complete response is worthy of further exploration as it may provide a means for identifying patients upfront who have the greatest likelihood of responding to treatment with onvansertib."

Key data and conclusions from the ASH presentation include:

- 9 of 45 (20%) evaluated patients achieved CR/CRi (5 in Phase 1b and 4 in Phase 2)
- 55% of responders had a mutation in a splicing factor
- As of the data cutoff, 2 patients proceeded to transplant following CR and 3 patients had ongoing responses
- 4 patients have achieved a durable response (≥9 months)
- Decreases in mutant ctDNA within the first treatment cycle appear to be highly correlated with clinical response; 7 of 7 (100%) patients with CR/CRi showed a decrease in mutant ctDNA after one cycle of treatment, while only 2 of 15 (13%) non-responders showed a similar decrease
- Data indicate that onvansertib in combination with decitabine is a safe and well-tolerated treatment regimen

The poster presentation from the 62nd Annual ASH meeting is available on the "Scientific Presentations" section of the Cardiff Oncology website at https://cardiffoncology.com/scientific-presentations/.

About the Phase 1b/2 Trial of Onvansertib in Relapsed/Refractory AML

Cardiff Oncology's ongoing Phase 1b/2 trial (NCT03303339) evaluating onvansertib in combination with decitabine in AML patients who are either treatment naïve and not candidates for induction therapy or who have relapsed or refractory disease after treatment with one prior regimen. Patients receive onvansertib, administered orally, on days 1 through 5 of each 21-28-day cycle in combination with decitabine. The primary efficacy endpoint of objective response (CR + CRi) is assessed in patients who complete at least 1 cycle of treatment.

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; 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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