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): **June 15, 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 June 15, 2020, Cardiff Oncology, Inc. (the "Company") issued a press release announcing presentation of final results of its Phase 1b study, and preliminary positive data from its Phase 2 study, in relapsed or refractory acute myeloid leukemia (AML). The data was presented as a virtual poster presentation at the European Hematology Association (EHA) annual conference. 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 June 15, 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: June 15, 2020

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Data Continues to Demonstrate Efficacy, Durability and Safety of Onvansertib in Patients with Difficult-to-Treat Relapsed/Refractory AML

- ***Phase 1b: 7 (33%) of evaluable patients achieved an objective response, with a complete response (CR/CRi) in 5 (31%) patients treated at the four highest onvansertib dose levels***
- ***3 (60%) of the 5 patients remain on treatment with durable response demonstrated: 6, 12 and 15 months, respectively, following the initial response; 1 patient went on to transplant***
- ***Phase 2: Of the 7 patients having completed 1 cycle of treatment, 2 (28%) achieved an objective response; 1 had a complete response (CR) and significant decrease in ctDNA***
- ***Response biomarkers show that decreases in ctDNA after 1 cycle of treatment are highly predictive of clinical response***
- ***Onvansertib in combination with decitabine continues to be a safe and well-tolerated treatment regimen***

SAN DIEGO (June 15, 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 presentation of final results of its Phase 1b study, and preliminary positive data from its Phase 2 study, in relapsed or refractory acute myeloid leukemia (AML). The data was presented as a virtual poster presentation at the European Hematology Association (EHA) annual conference.

The presentation highlighted the efficacy, durability of response, favorable safety and tolerability profile, as well as correlative biomarker data. Anti-leukemic activity was observed at a wide range of onvansertib doses (27 to 90 mg/m^2), indicating a large therapeutic window.

The EHA poster presentation is available for download from the Scientific Presentations page on the Cardiff Oncology website at https://cardiffoncology.com/scientific-presentations/.

“While the trial is still ongoing, we are encouraged by the efficacy we are seeing thus far in patients with relapsed/refractory AML, particularly the durability of response observed in some patients,” said Dr. Amer Zeidan, lead investigator and associate professor of Medicine at the Yale School of Medicine, and the medical director of Hematology Early Therapeutics Research at Yale Cancer Center. “As we continue with enrollment and assessment of efficacy in the Phase 2 portion of the trial, I look forward to seeing additional clinical benefit with the combination of onvansertib and decitabine in our patients in an indication that is in dire need of new safe and effective treatment options.”

Presentation Highlights

Safety and Tolerability:

- In Phase 1b, the maximum tolerated dose (MTD) was established at 60 mg/m^2 with no dose-limiting toxicities through this dose level

- Treatment-related toxicities continue to be primarily on-target hematological; with rash and mucositis being reported at higher onvansertib doses

Efficacy

Completed Phase 1b:

- Anti-leukemic activity was observed at a wide range of onvansertib doses (27 to 90 mg/m^2), indicating a large therapeutic window
- Of the 21 patients evaluable for efficacy in the completed Phase 1b dose escalation study, 7 (33%) achieved an objective response; 5 (31%) of 16 patients who achieved a complete response (CR/CRi) were treated at the four highest onvansertib dose levels (27 – 90 mg/m^2)
- 3 patients remain on treatment; time since clinical response is 6, 12 and 15 months, respectively

Ongoing Phase 2:

- Of the 7 patients completing 1 cycle of treatment as of the data cutoff, 28% achieved an objective response:
  - 1 patient achieved a CRi at cycle 1 and a CR at cycle 2; time since response is 3 months and the patient continues on treatment
  - 1 patient achieved a partial response at cycle 1 and remains on treatment

Biomarker Analysis:

- Decreases in mutant ctDNA after 1 cycle of treatment were highly predictive of clinical response
- Target engagement in circulating blasts was associated with greater decrease in bone marrow blasts

About the Phase 2 Clinical Trial of Onvansertib in AML

The Phase 2 AML trial (NCT03303339) of onvansertib in combination with decitabine will enroll 32 patients who are either treatment naïve and not candidates for induction therapy or who have relapsed disease after treatment with one prior regimen. Patients will 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) will be assessed in patients who complete at least 1 cycle of treatment.

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.

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), KRAS-mutated 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/Pfizer, Ignyta/Roche and Genentech.

About Cardiff Oncology, Inc.

Cardiff Oncology, Inc. (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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