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): September 14, 2020



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

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 StockCRDFNasdaq 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 ($\S230.405$ of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 ($\S240.12b-2$ of this chapter). Emerging growth company \Box

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 September 14, 2020, Cardiff Oncology, Inc. (the "Company") issued a press release announcing the publication of an abstract for an electronic poster to be presented as part of the European Society of Medical Oncology (ESMO) Virtual Congress 2020. 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 September 14, 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: September 14, 2020

CARDIFF ONCOLOGY, INC.

By: /s/ Mark Erlander

Mark Erlander Chief Executive Officer

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Cardiff Oncology to Present Data Further Demonstrating the Safety and Efficacy of Onvansertib in KRAS-Mutated Metastatic Colorectal Cancer Patients

SAN DIEGO (September 14, 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, castration-resistant prostate cancer and leukemia, today announced the publication of an abstract for an electronic poster to be presented as part of the <u>European Society of Medical</u> <u>Oncology (ESMO) Virtual Congress 2020</u>. The abstract highlights preliminary clinical data from the Company's ongoing Phase 1b/2 trial evaluating onvansertib in combination with FOLFIRI and bevacizumab for the second line treatment of patients with KRAS-mutated metastatic colorectal cancer.

The preliminary data published in the abstract continue to show the safety and efficacy of onvansertib, as well as the durability of response, in combination with FOLFIRI and bevacizumab in KRAS-mutated metastatic colorectal cancer patients on their second line of therapy. The data also show that changes in plasma KRAS mutation levels during the first cycle of treatment are predictive of clinical response.

Updated results from the ongoing Phase 1b/2 trial will be presented as part of the abstract's corresponding electronic poster. Details on the poster presentation are shown below:

Abstract ID: 2969 Presentation number: 436P Title: Phase 1b/2 Study of the Polo-like kinase 1 (PLK1) Inhibitor, Onvansertib, in Combination with FOLFIRI and Bevacizumab for Second Line Treatment of KRAS-Mutated Metastatic Colorectal Cancer Session Name: Poster Display Session Presentation Date: September 17, 2020

The electronic poster will be available on the "Scientific Presentations" section of the Cardiff Oncology website at <u>https://cardiffoncology.com/scientific-presentations/</u>.

About the Phase 1b/2 Trial of Onvansertib in Metastatic KRAS-mutated Colorectal Cancer

Cardiff Oncology's ongoing clinical trial is a multi-center, single-arm Phase 1b/2 study assessing the safety and preliminary efficacy of onvansertib in combination with FOLFIRI and bevacizumab in second line treatment of patients with KRAS-mutated metastatic colorectal cancer (mCRC). Trial participants are treated with onvansertib on Days 1-5, and FOLFIRI and bevacizumab on Day 1, of 14-day cycles. Primary outcome measures include safety and tolerability assessments. Secondary outcome measures include preliminary efficacy determined by radiographic scans every 8 weeks and reduction in KRAS mutant allelic burden evaluated by liquid biopsy. The trial is being conducted at the USC Norris Comprehensive Cancer Center and the three Mayo Clinic Cancer Centers. For more information on the trial, please visit https://clinicaltrials.gov/ct2/show/NCT03829410.

About Cardiff Oncology, Inc.

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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 ongoing clinical programs that are demonstrating the safety and efficacy of onvansertib: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/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; 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 paver 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

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not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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