

**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 6, 2022**



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 September 6, 2022, Cardiff Oncology, Inc. issued a press release announcing the publication of two abstracts that have been accepted for poster presentations at the European Society for Medical Oncology (ESMO) Congress 2022, which is taking place both virtually and at the Paris Expo Porte de Versailles in Paris, France from September 9 – 13, 2022. 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 6, 2022.](#)

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 6, 2022

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Announces Upcoming Poster Presentations at the ESMO Congress 2022

SAN DIEGO, September 6, 2022 – Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced the publication of two abstracts that have been accepted for poster presentations at the European Society for Medical Oncology (ESMO) Congress 2022, which is taking place both virtually and at the Paris Expo Porte de Versailles in Paris, France from September 9 – 13, 2022.

The full texts of the published abstracts can be found on the ESMO Congress 2022 website. Details on the corresponding posters are shown below.

| | |
|-----------------------|--|
| Poster Title: | The PLK1 Inhibitor Onvansertib Overcomes Irinotecan Resistance in RAS-mutated (mRAS) Metastatic Colorectal Cancer (mCRC) In Vivo and in Patients |
| Speaker: | Scott Kopetz, M.D., Ph.D. |
| Poster Number: | 366P |
| Session Title: | Poster Session 7 |
| Session Date: | September 11, 2022 |
| Session Hours: | 9:00 AM – 5:00 PM CEST |
| Location: | Poster Area, Hall 4 |

The abstract includes findings from an Expanded Access Program (EAP) in which patients with KRAS-mutated metastatic colorectal cancer (mCRC) who failed or progressed on standard-of-care, including irinotecan, were treated with onvansertib in combination with FOLFIRI/bevacizumab. These findings showed that early changes in KRAS mutant allelic frequency (MAF) were associated with increased benefit in the EAP. In addition, the abstract includes results from murine studies in patient-derived xenograft (PDX) models of RAS-mutated, irinotecan-resistant colorectal cancer. These data, together with findings from the EAP, suggest onvansertib can overcome irinotecan resistance in RAS-mutated colorectal cancer. Additional findings from the EAP and data from murine studies will be announced during the upcoming congress, in accordance with ESMO's embargo policies.

Poster Title: Early Decreases in KRAS Mutant Allele Frequency (MAF) Predicts Clinical Benefit to the PLK1 Inhibitor Onvansertib in Combination with FOLFIRI/bev in 2L treatment of metastatic colorectal carcinoma (mCRC)

Speaker: Heinz-Josef Lenz, M.D.

Poster Number: 397P

Session Title: Poster Session 8

Session Date: September 11, 2022

Session Hours: 9:00 AM – 5:00 PM CEST

Location: Poster Area, Hall 4

The abstract includes data from an ongoing Phase 1b/2 trial evaluating onvansertib in combination with FOLFIRI/bevacizumab in second-line KRAS-mutated mCRC. The data show that the subset of patients with $\geq 90\%$ decreases in KRAS MAF in circulating tumor DNA after one cycle of treatment had a significantly greater objective response rate and significantly longer progression-free survival compared to the subset of patients with decreases in KRAS MAF $< 90\%$. Additional findings from the trial will be announced during the upcoming congress, in accordance with ESMO's embargo policies.

Clinical and Corporate Update Conference Call and Webcast

Cardiff Oncology will host a webcast and conference call to provide a clinical and corporate update on Monday, September 12, 2022 at 4:30 PM ET. The event will feature discussions on the planned development pathway for onvansertib in KRAS-mutated metastatic colorectal cancer and updates on other development programs. In addition, company management will provide data updates from ongoing clinical trials. To access the call, please dial 1-877-407-9208 (domestic) or 1-201-493-6784 (international) and refer to conference ID 13731618. The conference call will also be webcast live and a link to the webcast can be accessed [here](#). A replay of the webcast will be available by visiting the "[Events](#)" section of the Cardiff Oncology website after its conclusion.

About Cardiff Oncology, Inc.

Cardiff Oncology is a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers. Our lead asset is onvansertib, a PLK1 inhibitor we are evaluating in combination with standard-of-care (SOC) therapeutics in clinical programs targeting indications such as KRAS-mutated metastatic colorectal cancer, metastatic pancreatic ductal adenocarcinoma, and metastatic castrate-resistant prostate cancer. These programs and our broader development strategy are designed to target tumor vulnerabilities in order to overcome treatment resistance and deliver superior clinical benefit compared to the SOC. 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 using 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 several 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, 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; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. There are no guarantees that our product candidate 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, 2021, 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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