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): **April 8, 2022**

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 7.01 Regulation FD Disclosure.

On April 8, 2022, Cardiff Oncology, Inc. (the "Company") issued a press release announcing updated clinical data and new biomarker analyses from its ongoing Phase 2 trial of onvansertib in combination with abiraterone/prednisone in metastatic castrate-resistant prostate cancer (mCRPC) patients. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K. In addition, the Company issued a press release announcing the results of preclinical studies evaluating the anti-cancer activity of onvansertib in combination with the PARP inhibitor (PARPi) olaparib in PARPi-resistant patient-derived xenograft (PDX) ovarian cancer models. A copy of the press release is furnished as Exhibit 99.2 to this Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1	Press Release of Cardiff Oncology, Inc. dated April 8, 2022.
99.2	Press Release of Cardiff Oncology, Inc. dated April 8, 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: April 8, 2022

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Announces Updated Clinical and New Biomarker Data from Phase 2 Metastatic Castration-Resistant Prostate Cancer Trial at the AACR Annual Meeting

- Trial evaluates onvansertib in combination with abiraterone and prednisone in metastatic castration-resistant prostate cancer (mCRPC) patients showing initial abiraterone resistance by rising PSA

- Disease control increased with increasing dose density of onvansertib from 29% to 45% of patients achieving PSA stabilization and from 53% to 75% of patients with radiographic stable disease; Arm A (n=17) – onvansertib 24mg/m^2 days 1-5 in 21-day cycle to Arm C (n=20) – 12mg/m^2 days 1-14 in 21-day cycle

- Median progression-free survival (mPFS) has increased with increasing onvansertib dose density from 4.1 months in Arm A to 13.2 months to-date in Arm C patients

- Genomic analysis of ctDNA showed a correlation between alterations in two key genes of the PI3K signaling pathway—MTOR and PTEN, which appears to underly increased pathway activity, and sensitivity to onvansertib/abiraterone combination in mCRPC patients with early abiraterone resistance

SAN DIEGO, April 8, 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 updated clinical data and new biomarker analyses from its ongoing Phase 2 trial of onvansertib in combination with abiraterone/prednisone in metastatic castrate-resistant prostate cancer (mCRPC) patients. The data are featured in a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting, which is taking place both virtually and in-person at the Ernest N. Morial Convention Center in New Orleans, Louisiana from April 8-13, 2022.

“Results from the mCRPC trial demonstrate clinically meaningful disease control rates in patients showing early resistance to abiraterone,” said David Einstein, M.D., principal investigator at Beth Israel Deaconess Medical Center. “As the dose density of onvansertib was increased in three consecutive Arms (A, B and C), we observed an increase in disease control rates with both PSA stabilization and radiographic stable disease twelve weeks into treatment and some of these patients have experienced durable stabilization. Pre-clinical data suggest that the synergistic effect is independent of androgen receptor signaling.”

The primary efficacy endpoint of the mCRPC trial is disease control rate at 12 weeks (12-week DCR), which is defined by a decline or stabilization of PSA levels (rise of <25% over baseline or less than 2 ng/mL). Each of the trial’s three arms has evaluated a different dosing schedule of onvansertib alongside abiraterone and prednisone administered throughout the respective treatment cycle. Arm A evaluated 24 mg/m^2 onvansertib on Days 1-5 of 21-day cycles, Arm B evaluated 18 mg/m^2 onvansertib on Days 1-5 of 14-day cycles, and Arm C is evaluating 12 mg/m^2 onvansertib on Days 1-14 of 21-day cycles.

“Biomarker correlative studies have revealed significant and positively associated mutations in MTOR, FAT1, PTEN and FOXA1, with tumors harboring these mutations achieving stable disease or a partial response within the initial abiraterone-resistant setting,” said Tod Smeal, Ph.D., chief scientific officer of Cardiff Oncology. “In addition, gene expression signatures from patient tumor tissue biopsies correlated with treatment response included those corresponding to the ERG+ and Notch pathways, which are involved in cell-invasion, epithelial-mesenchymal transition and metastasis. We continue to examine these promising biomarker studies with the goal of identifying the genomic alterations most closely associated with response to the combination regimen of onvansertib and abiraterone.” Key data and conclusions from the AACR poster (cut-off date of February 2, 2022) and ongoing trial include:

Efficacy:

- 75% (15/20) of evaluable patients in Arm C, which represents the most dose dense treatment schedule, showed disease control by radiographic SD/PR at 12-weeks, compared to 53% (9/17) and 58% (11/19) in the less dose dense Arms A and B, respectively

Biomarker:

- Treatment response (SD/PR) was positively associated with mutations in PTEN and MTOR, key genes in the PI3K signaling pathway
- Gene signatures correlating with treatment response included those corresponding to the ERG+ and Notch pathways, which are involved in cell-invasion, epithelial-mesenchymal transition and metastasis
- Genes related to mitochondrial and immune functions were downregulated in patients achieving SD or a PR compared to those showing progressive disease

Safety:
- The treatment regimen of onvansertib in combination with abiraterone/prednisone has been well tolerated

An electronic copy of the poster and corresponding abstract, entitled, *Biomarkers of response to abiraterone and the polo-like kinase 1 (PLK1) inhibitor onvansertib in metastatic castration resistant prostate cancer (mCRPC) patients*, is available to registered attendees of the AACR annual meeting on the meeting website. The in-person presentation will take place during the "Biomarkers Predictive of Therapeutic Benefit 1" poster session on April 11, 2022, from 9:00 AM – 12:30 PM CT. Following the meeting, the poster will be available on the "Scientific Presentations" section of the Cardiff Oncology website at https://cardiffoncology.com/scientific-presentations/.

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, an oral highly selective PLK1 inhibitor, which 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 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, 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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Cardiff Oncology Announces Data Showing the Combination of PARP Inhibition with Onvansertib Overcomes PARP Inhibitor Resistance in BRCA1-mutant and Wildtype Patient-Derived Xenograft Ovarian Cancer Models

- Combining onvansertib with the PARP inhibitor (PARPi) olaparib led to statistically significant survival benefits compared to treatment with either agent alone in PARPi-resistant ovarian cancer models
- Onvansertib-olaparib combination was well tolerated *in vivo*

SAN DIEGO, April 8, 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 results of preclinical studies evaluating the anti-cancer activity of onvansertib in combination with the PARP inhibitor (PARPi) olaparib in PARPi-resistant patient-derived xenograft (PDX) ovarian cancer models. The results are featured in a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting, which is taking place both virtually and in-person at the Ernest N. Morial Convention Center in New Orleans, Louisiana from April 8-13, 2022.

“In these studies, we sought to evaluate how combining onvansertib with PARP inhibition, an approved maintenance treatment for ovarian cancer, might mitigate the known phenomenon of acquired tumor resistance to PARP inhibitors,” said Tod Smeal, Ph.D., chief scientific officer at Cardiff Oncology. “We are very pleased with the results, which showed onvansertib and olaparib synergistically combining to generate strong activity against PARPi-resistant patient-derived ovarian cancer models. Given the current lack of effective treatment options for patients showing PARPi resistance, we believe these data are supportive of evaluating this combination within a PARPi-resistant clinical setting.”

Preclinical studies featured in the AACR poster evaluated onvansertib-olaparib combination treatment in three olaparib-resistant patient-derived xenograft (PDX) ovarian cancer models. Two of the three PDX models used (MNHOC22, MNHOC266) were cisplatin-sensitive with a mutated *BRCA1* gene, while the third (MNHOC316DDP) was cisplatin-resistant with wild type *BRCA1*. *BRCA1*-mutant tumor cells are deficient for homologous recombination (HR)-mediated DNA repair and are initially sensitive to PARPi. This suggests that PARPi resistance was acquired in the MNHOC22 and MNHOC266 tumors due to the restoration of HR-mediated DNA repair, while being naturally conferred in MNHOC316DDP tumors due to continuous HR-proficiency.

Data showed that combining onvansertib with olaparib led to a statistically significant survival benefit compared to treatment with either agent alone in each of the three evaluated PDX models. Results showed the combination was well tolerated.

An electronic copy of the poster and corresponding abstract, entitled, *Combining PARP inhibition with the Polo-like kinase 1 (PLK1) inhibitor onvansertib overcomes PARP inhibitor resistance*, is available to registered attendees of the AACR annual meeting on the meeting website. The in-person presentation will take place during the “Drug Resistance and Reversal of Resistance” poster session on April 12, 2022, from 1:30 PM – 5:00 PM CT. Following the meeting, the poster will be available on the "Scientific Presentations" section of the Cardiff Oncology website at https://cardiffoncology.com/scientific-presentations/.

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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 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, 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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