

**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): **January 11, 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 January 11, 2022, Cardiff Oncology, Inc. issued a press release announcing the appointments of Tod Smeal, Ph.D., as chief scientific officer (CSO) and Charles Monahan, RPh, as senior vice president, regulatory affairs. 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 January 11, 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: January 11, 2022

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Appoints Tod Smeal, Ph.D., as Chief Scientific Officer and Charles Monahan, RPh, as Senior Vice President, Regulatory Affairs

- Dr. Smeal has over 20 years of industry experience developing targeted therapies and previously served as CSO of Cancer Biology at Eli Lilly and Company, and director of Pfizer Oncology Research Unit
- Mr. Monahan is a registered pharmacist with over 20 years of regulatory experience developing drugs and biologics for oncology, infectious diseases, and ocular indications

SAN DIEGO, January 11, 2022 -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage oncology company, developing new precision medicine treatment options for cancer patients in indications with the greatest unmet medical need including KRAS-mutated colorectal cancer, pancreatic cancer, and castrate-resistant prostate cancer, today announced the appointments of Tod Smeal, Ph.D., as chief scientific officer (CSO) and Charles Monahan, RPh, as senior vice president, regulatory affairs.

“We are excited to welcome Tod and Charles to Cardiff Oncology as we approach key inflection points in onvansertib’s development,” said Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology. “Tod has a wealth of expertise and experience bringing targeted, first-of-their-kind cancer therapeutics from preclinical development to launch, and Charles brings a valuable perspective on regulatory pathways to approval of novel cancer drugs through his vast experience in the pharmaceutical industry. We’re grateful to have their deep understanding of the oncology landscape in which we intend to advance onvansertib, so that we can maximize its success as we work to improve treatment options and outcomes for patients with historically difficult-to-treat cancers.”

Dr. Smeal added, “Onvansertib’s ability to sensitize cancer cells to currently available therapeutic agents give this versatile molecule immense potential to close gaps in a wide range of oncology treatment regimens. I am eager to begin working to advance Cardiff Oncology’s clinical pipeline and look forward to leading our efforts to enable its expansion into additional indications.”

Mr. Monahan commented, “Cardiff Oncology’s robust clinical dataset demonstrates the potential of onvansertib in combination with standard-of-care therapy to add significant clinical benefit across a number of cancer indications. I am thrilled to have the opportunity to lead our efforts through the regulatory process and will work with my new colleagues to advance onvansertib towards registration as expeditiously as possible.”

Appointee Bios

Dr. Smeal joins Cardiff Oncology following roles as chief scientific officer at Hexagon Bio, chief scientific officer of Cancer Biology at Eli Lilly and Company, director of the Oncology Research Unit of Pfizer, and senior group leader at the SUGEN site of Pharmacia and Upjohn and SUGEN. With over 20 years in industry working on targeted therapies, Dr. Smeal has played key leadership roles in delivering about 20 first-in-human drugs/new medical entities and several FDA-approved or soon-to-be approved drugs, including Lorbrena, Xalkori, Vizimpro and Nirogacestat. Dr. Smeal's work in developing cancer therapies has been focused on intracellular signaling, kinases, drug pharmacology, and targeted therapies and their resistance mechanisms. Prior to his career in industry, Dr. Smeal was a post-doctoral fellow of the American Cancer Society and a senior post-doctoral fellow of the MIT-Merck fellowship program. Dr. Smeal holds a B.S. in biology from the Massachusetts Institute of Technology and a Ph.D. in biology from the University of California, San Diego.

Mr. Monahan joins Cardiff Oncology following a role as the global head of regulatory affairs for Erytech PharmaSA, where he led the regulatory strategy and execution of the company’s lead asset across multiple oncology indications in both the United States and Europe. Prior to Erytech, Mr. Monahan held senior regulatory positions at several pharmaceutical companies including Millennium Pharmaceuticals,

Molecular Insight Pharmaceuticals, AVEO Pharmaceuticals, and Transgene SA. In these roles, he worked on projects covering all stages of drug development, from preclinical through post-commercialization. Mr. Monahan is a registered pharmacist with extensive experience in clinical pharmacy, healthcare management, and pharmaceutical development and has over 20 years of regulatory experience developing drugs and biologics for oncology, infectious diseases, and ocular indications. He holds a B.S. in pharmacy from the University of Rhode Island and a M.S. in regulatory affairs and health policy from the Massachusetts College of Pharmacy and Health Sciences.

Inducement Grant Under Nasdaq Listing Rule 5635(c)(4)

In connection with Dr. Smeal joining Cardiff Oncology, the Company's Board of Directors approved the grant of non-qualified stock options to purchase 275,088 shares of Cardiff Oncology common stock outside of the Cardiff Oncology 2021 Omnibus Equity Incentive Plan. The stock option was granted as an inducement material to Dr. Smeal becoming an employee of Cardiff Oncology in accordance with Nasdaq Listing Rule 5635(c)(4). The option was granted as of January 10, 2022, and has an exercise price of \$6.58 per share, the closing price on the grant date. The option vests over four years with 25% vesting after 12 months and the remaining shares vesting monthly over the following 36-months, subject to Dr. Smeal's continued employment with Cardiff Oncology on such vesting dates.

About Cardiff Oncology, Inc.

Cardiff Oncology is a clinical-stage oncology company, developing new precision medicine treatment options for cancer patients in indications with the greatest unmet medical need. Our goal is to target tumor vulnerabilities with treatment combinations that overcome disease resistance and improve disease response to standard treatment regimens and to 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 anti-cancer therapeutics. Our clinical development programs incorporate tumor genomics and biomarker technology to refine assessment of patient response to treatment. We have three clinical programs currently ongoing: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® (bevacizumab) in KRAS-mutated metastatic colorectal cancer (mCRC); a Phase 2 trial of onvansertib in combination with nanoliposomal irinotecan, leucovorin and fluorouracil for the second-line treatment of patients with metastatic pancreatic ductal adenocarcinoma (PDAC); and a Phase 2 study of onvansertib in combination with Zytiga® (abiraterone)/prednisone in metastatic castrate-resistant prostate cancer (mCRPC). 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, 2020, 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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