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): **February 25, 2021**

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:

☐ 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 2.02 Results of Operations and Financial Conditions.

On February 25, 2021, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the fourth quarter and full year ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 Press Release of Cardiff Oncology, Inc. dated February 25, 2021.

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: February 25, 2021

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Announces Fourth Quarter and Full Year 2020 Results and Recent Highlights

SAN DIEGO (February 25, 2021) – Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company developing drugs to treat cancers with the greatest medical need for new treatment options, including KRAS-mutated colorectal cancer, pancreatic cancer, castrate-resistant prostate cancer and leukemias, today announced recent company highlights and financial results for the fourth quarter and full year ended December 31, 2020.

"Over the last several months we achieved key clinical milestones, which provided the momentum for our successful raise of over $100 million. Together, these events have enabled us to accelerate the execution of our clinical programs and expand our pipeline to other relevant cancer indications," said Dr. Mark Erlander, chief executive officer of Cardiff Oncology. "Data from our lead KRAS-mutated metastatic colorectal cancer (mCRC) program show promising and durable efficacy, highlighting the potential of onvansertib in combination with standard-of-care FOLFIRI (irinotecan and 5-FU)/bevacizumab to address the need for a new second-line treatment option. Importantly, we completed enrollment in the Phase 1b portion of this trial in December of 2020 and initiated patient accrual in the Phase 2 segment in January of this year. Based on the mCRC trial results, we are leveraging the known synergy of onvansertib with irinotecan and 5-FU by evaluating this combination (nanoliposoamal irinotecan and 5-FU) in pancreatic ductal adenocarcinoma (PDAC). Approximately 95% of PDAC patients have a KRAS mutation and current second-line treatment for this indication conveys only a 7.7% response rate and 6-month median overall survival benefit. We plan to initiate a Phase 2 trial in this indication in the first half of the year following the receipt of our "study may proceed" notification from the FDA last month. Our goal is to further demonstrate the broad applicability of onvansertib across KRAS-mutated cancers and to address an indication with a significant unmet need for new treatment options."

Dr. Erlander continued, "Onvansertib's broad applicability extends beyond targeting KRAS-mutated cancers, as shown by the exciting progress of our metastatic castrate-resistant prostate cancer (mCRPC) trial. The addition of onvansertib to daily abiraterone treatment in patients showing initial resistance to abiraterone has resulted in durable disease control. Notably, the most recent data presented at ASCO-GU showed a significant increase in disease control rate in patients receiving onvansertib for more days within a treatment cycle. Looking ahead, the progress we've made across our clinical programs leaves us poised to achieve a steady cadence of catalysts throughout 2021 and beyond as we continue to advance onvansertib's development."

Program highlights for the quarter ended December 31, 2020 include:

Corporate Milestones:

Raised gross proceeds of approximately $100 million in an offering of common stock

Cardiff Oncology substantially strengthened its balance sheet in the fourth quarter, closing an underwritten public offering of 6,500,000 shares of its common stock at a public offering price of $13.50 per share, before deducting underwriter discounts and commissions and estimated offering expenses. The underwriters also exercised an option to purchase an additional 975,000 shares at the public offering price (less the underwriting discounts and commissions). The Company intends to use the net proceeds

from this offering for clinical development of onvansertib, working capital and for other general corporate purposes.

Appointed Dr. Rodney Markin as Chairman of the Board

Prior to being appointed Chairman, Dr. Markin previously served as a Director on Cardiff's Board from February 2014 to December 2020. He has extensive medical expertise and experience in institutional healthcare, and is currently the Vice President for Network Development, Nebraska Medicine and Associate Vice Chancellor for Business and Executive Director of the UNeTech Institute at the University of Nebraska Medical Center. In addition to currently holding several other distinguished positions in academia, Dr. Markin also has served on the boards of Perceptimed Inc. since 2014, MikroScan Technologies Inc. since 2015, Afaxys Inc. since 2017 and Paradigm Diagnostics Inc. since 2018.

Metastatic Castrate-Resistant Prostate Cancer (mCRPC) Program:

Identified a biomarker associated with onvansertib-abiraterone synergy that is enriched in mCRPC patients with the clinically defined basal molecular tumor subtype

Collaborative studies with the Massachusetts Institute of Technology and Decipher Biosciences identified a gene signature (biomarker) related to cell division pathways that can be used to predict which cancer cells will show a synergistic anti-tumor response to treatment with onvansertib in combination with abiraterone. This gene signature is correlated with the clinically defined basal molecular subtype of mCRPC, suggesting that patients with this tumor subtype may be more likely to respond to onvansertib-abiraterone combination therapy. These studies were featured in an electronic poster at the 27th Annual Prostate Cancer Foundation Scientific Retreat.

Acute Myeloid Leukemia (AML) Program:

Presented data at ASH demonstrating the safety and anti-leukemic activity of onvansertib in relapsed/refractory AML

Updated data from a Phase 1b/2 clinical trial evaluating onvansertib in combination with decitabine in relapsed/refractory AML patients were featured in a virtual oral poster presentation at the 62nd American Society of Hematology (ASH) Annual Meeting. These data demonstrated the safety, tolerability and anti-leukemic activity of the onvansertib-decitabine combination and showed an over-representation of splicing factor mutations in patients achieving a complete response. Additional highlights from the presentation included:

- 9 of 45 (20%) evaluated patients achieved a complete remission with or without hematologic count recovery (CR/CRi - 5 in Phase 1b and 4 in Phase 2)
- 55% of responders had a mutation in a splicing factor
- 2 patients proceeded to transplant following CR and 3 patients had ongoing responses as of the ASH data cutoff
- 4 patients have achieved a durable response (≥9 months) – as of data cut-off date
- Decreases in mutant circulating tumor DNA (ctDNA) within the first treatment cycle appeared to be highly correlated with clinical response; 7 of 7 (100%) patients with CR/CRi showed a decrease

in mutant ctDNA after one cycle of treatment, while only 2 of 15 (13%) non-responders showed a similar decrease
- Data demonstrated that onvansertib in combination with decitabine is a safe and well-tolerated treatment regimen

Highlights for the period subsequent to the quarter end include:

KRAS-mutated Metastatic Colorectal Cancer (mCRC) Program:
Announced updated data from its Phase 1b/2 trial evaluating onvansertib plus FOLFIRI (irinotecan and 5-FU)/bevacizumab in second line KRAS-mutated mCRC patients and initial findings from its Expanded Access Program (EAP)

In conjunction with the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI), Cardiff Oncology announced updated Phase 1b data demonstrating the clinical benefit of onvansertib in KRAS-mutated mCRC, as well as initial findings from its EAP. Data highlights from the Phase 1b trial, as of January 6, 2021, include:

- 12 of 14 (86%) evaluable patients achieved a clinical benefit (SD – stable disease plus PR – partial response)
- 5 of 14 (36%) evaluable patients achieved a PR; 4 patients had a confirmed PR; 1 patient went on to have curative surgery; 1 patient with a non-confirmed PR went off study following PR due to a treatment-unrelated AE
- 3 patients with SD remain on treatment, including 2 who have yet to have their 16-week (second) scan; time to achieving a PR ranges from 2 to 6 months in trial participants on treatment
- Clinical responses were observed across different KRAS variants, including the 3 most common in colorectal cancer
- Patients achieving a PR or SD showed the greatest decrease in plasma mutant KRAS after one cycle of therapy
- The combination of onvansertib and FOLFIRI/bevacizumab was well tolerated

Enrollment of patients in the Phase 1b segment of the trial is complete and the recommended Phase 2 dose of onvansertib has been confirmed at 15 mg/m^2. The Phase 2 segment of the trial is open to full enrollment of approximately 26 patients across 6 trial sites: USC Norris Comprehensive Cancer Center, Mayo Clinic Cancer Centers (Arizona, Rochester, Jacksonville), Kansas University Medical Center and CARTI Cancer Center.

In the EAP, Cardiff Oncology announced that 6 of the initial 9 patients treated showed tumor shrinkage and remained on treatment with durable responses lasting an average of 6 months. Notably, 5 different KRAS mutation subtypes were represented amongst these patients and most patients had received prior treatment with FOLFIRI and progressed before enrolling in the EAP.

Metastatic Castrate-Resistant Prostate Cancer (mCRPC) Program:

Announced updated Phase 2 data showing a two-fold increase in efficacy with an optimized onvansertib dosing schedule

Updated data from a Phase 2 trial evaluating the all-oral combination of onvansertib, abiraterone and prednisone in patients showing initial abiraterone resistance were featured in a virtual oral poster presentation at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO-GU). These data showed that increasing the number of days of treatment with onvansertib from 5 to 14 in a 21-day cycle was associated with a greater than two-fold increase (29% to 63%) in disease control rate (DCR) at 12 weeks, the trial's primary efficacy endpoint. Across all cohorts, the DCR at 12 weeks is 35% (13/37), indicating the trial is on track to meet the stated criteria for success on its primary efficacy endpoint (30% DCR at 12 weeks). Additional highlights from the presentation included:

- The optimized dosing schedule of cohort C shows a greater than two-fold improvement in disease control rate compared to cohorts A and B
    - 63% (5/8) of cohort C patients achieved the primary efficacy endpoint compared to 29% (5/17) and 25% (3/12) of cohort A and B patients, respectively
- 75% (6/8) of evaluable patients in cohort C had radiographic stable disease (SD) at 12 weeks, compared to 53% (9/17) in cohort A, 42% (5/12) in cohort B and 54% (20/37) across all cohorts
- All cohort C patients achieving the primary efficacy endpoint remain on treatment
- Data show that the combination of onvansertib and abiraterone is well tolerated across the three different dosing schedules of cohorts A-C:
    - Cohort A: 24 mg/m^2 onvansertib on Days 1-5 of 21-day cycles, plus abiraterone and prednisone beginning on Day 1 and continuing uninterrupted throughout each cycle
    - Cohort B: 18 mg/m^2 onvansertib on Days 1-5 of 14-day cycles, plus abiraterone and prednisone beginning on Day 1 and continuing uninterrupted throughout each cycle
    - Cohort C: 12 mg/m^2 onvansertib on Days 1-14 of 21-day cycles, plus abiraterone and prednisone beginning on Day 1 and continuing uninterrupted throughout each cycle

Metastatic Pancreatic Ductal Adenocarcinoma (PDAC) Program:

Received "Study May Proceed" letter from the U.S. Food and Drug Administration (FDA) to begin a Phase 2 trial of onvansertib in metastatic PDAC

The Phase 2 clinical trial of onvansertib in metastatic PDAC is designed to assess the safety and preliminary efficacy of onvansertib in combination with nanoliposomal irinotecan (Onyvide®), leucovorin and fluorouracil (5-FU) as a second-line treatment in patients with metastatic PDAC who have failed first-line gemcitabine-based therapy. Onvansertib's potential in PDAC, where ~95% of patients have a KRAS mutation, is supported by the promising clinical data seen in the KRAS-mutated mCRC trial evaluating onvansertib in combination with irinotecan and 5-FU (FOLFIRI). Initiation of the Phase 2 trial is expected in the first half of 2021.

Fourth Quarter Financial Results:

As of December 31, 2020, Cardiff Oncology had approximately $131 million in cash and cash equivalents.

Net cash used in operating activities in the fourth quarter of 2020 was $5.1 million, an increase of $1.8 million from $3.3 million for the same period in 2019. The increase is attributed mainly to outside services and professional fees, facilities and other and changes in operating assets and liabilities.
Research and development expenses increased by approximately $0.3 million to $3.2 million for the three months ended December 31, 2020, from $2.9 million for the same period in 2019. The increase in

research and development expenses was primarily due to the increased outside service costs and clinical studies for advancing the development of our drug candidate, onvansertib. We expect increases in research and development costs to continue as we advance the onvansertib clinical development programs.

Selling, general and administrative expenses increased by approximately $1.9 million to $3.4 million for the three months ended December 31, 2020, from $1.5 million for the same period in 2019. The increase is primarily due to a one time increase in stock compensation expense, and outside services and professional fees.

About Cardiff Oncology, Inc.
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 clinical programs that have demonstrated the safety and efficacy of onvansertib: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® (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). A new 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) is planned for initiation in the first half of 2021. 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, 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, 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.

Cardiff Oncology Contact:
Vicki Kelemen
Chief Operating Officer
858-952-7652
vkelemen@cardiffoncology.com

Investor Contact:
Joyce Allaire
LifeSci Advisors
212-915-2569
jallaire@lifesciadvisors.com

Media Contact:
Karen O'Shea, Ph.D.
LifeSci Communications
929-469-3860
koshea@lifescicomms.com

Cardiff Oncology, Inc.
Condensed Statements of Operations
(in thousands, except for per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
Revenues:				
Royalties	$ 119	$ 93	$ 366	$ 243
Services	—	—	—	2
Total revenues	119	93	366	245
Costs and expenses:				
Research and development	3,199	2,865	11,235	11,162
Selling, general and administrative	3,417	1,517	8,217	5,761
Total operating expenses	6,616	4,382	19,452	16,923
Loss from operations	(6,497)	(4,289)	(19,086)	(16,678)
Net interest income	21	46	88	234
Gain (loss) from change in fair value of derivative financial instruments warrants	(95)	1	(281)	28
Other (loss) income, net	(26)	—	(28)	2
Net loss	(6,597)	(4,242)	(19,307)	(16,414)
Preferred Stock Dividend	(6)	(6)	(3,290)	(293)
Net loss attributable to common stockholders	$ (6,603)	$ (4,248)	$ (22,597)	$ (16,707)
Net loss per common share - basic and diluted	$ (0.19)	$ (0.51)	$ (1.08)	$ (2.80)
Weighted-average shares outstanding - basic and diluted	35,566	8,329	20,875	5,974

Cardiff Oncology, Inc.
Condensed Balance Sheets
(in thousands)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 130,981	$ 10,195
Accounts receivable and unbilled receivable	320	204
Prepaid expenses and other assets	2,055	955
Total current assets	133,356	11,354
Property and equipment, net	624	878
Operating lease right-of-use assets	343	697
Other assets	404	158
Total Assets	$ 134,727	$ 13,087
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,366	$ 656
Accrued liabilities	3,851	3,260
Operating lease liabilities	860	866
Other current liabilities	42	—
Total current liabilities	6,119	4,782
Derivative financial instruments warrants	285	4
Operating lease liabilities, net of current portion	9	861
Other liabilities	156	129
Total Liabilities	6,569	5,776
Stockholders' equity	128,158	7,311
Total liabilities and stockholders' equity	$ 134,727	$ 13,087

Cardiff Oncology, Inc.
Condensed Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2020	**2019**
Operating activities		
Net loss	$ (19,307)	$ (16,414)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment loss	34	—
Depreciation and amortization	466	494
Stock based compensation expense	1,765	885
Change in fair value of derivative financial instruments - warrants	281	(28)
Release of clinical trial funding commitment	1,100	703
Changes in operating assets and liabilities	(654)	1,092
Net cash used in operating activities	(16,315)	(13,268)
Investing activities:		
Capital expenditures	(212)	(68)
Net cash used in investing activities	(212)	(68)
Financing activities:		
Proceeds from sales of common stock, preferred stock and warrants, net of expenses	112,300	8,818
Costs related to the clinical trial funding commitment	(7)	(40)
Proceeds from exercise of warrants	24,872	3,300
Proceeds from exercise of options	148	—
Borrowings under note payable	305	—
Repayments of note payable	(305)	—
Net cash provided by financing activities	137,313	12,078
Net change in cash and cash equivalents	120,786	(1,258)
Cash and cash equivalents Beginning of period	10,195	11,453
Cash and cash equivalents End of period	$ 130,981	$ 10,195